No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

APPELLEES' APPENDIX
VOLUME 4 OF 10 (Tabs 175-26 – 176-9)

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TAB 175-26 (continued)

1) Perform yearly breast examinations and patients should perform self-examinations of the breasts every month. Mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results [5][19][7][13][38][35][8][11][12][69][14][15][94].

2) Monitor blood pressure at regular intervals during estrogen use [5][7][13][38][35][8][11][12][14][15][94].

3) Observe carefully for exacerbation of conditions in patients with conditions that may be influenced by fluid retention such as cardiac or renal dysfunction [5][19][7][13][38][35][8][11][12][69][14][15][94].

4) Periodic monitoring of bone maturation and effects on epiphyseal centers is recommended when estrogen is administered to patients whose bone growth is not complete [10][7][8][11][12][14][94].

5) Directed or random endometrial sampling, when indicated, should be performed to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding [5].

B) Estradiol Acetate

1) Therapeutic

a) Laboratory Parameters

1) Measurement of serum FSH and estradiol levels have not been shown to be useful [59].

b) Physical Findings

1) Postmenopausal Vasomotor Symptoms

a) Estrogen administration and dosage should be guided by individual patient clinical response rather than by hormone levels when treating postmenopausal vasomotor symptoms [61]

b) Periodically reevaluate the need for continued treatment [59].

2) Postmenopausal Vulvar and Vaginal Atrophy

a) Improvement in vulvar or vaginal atrophy is indicative of efficacy.

b) Periodically reevaluate the need for continued treatment [59].

2) Toxic

a) Laboratory Parameters

1) Monitor thyroid function in women dependent on thyroid hormone replacement therapy [59].

2) Perform adequate diagnostic measures, including endometrial sampling, as clinically indicated in women with undiagnosed persistent or recurring abnormal vaginal bleeding [59].

b) Physical Findings

1) Carefully evaluate patients for ulceration or erosion of the vaginal or bladder wall [59].

2) Perform yearly breast examinations in all patients and schedule mammography examinations based on patient age, risk factors, and prior mammogram results [59].

3) Carefully observe patients for fluid retention in women who may be affected (eg, cardiac or renal impairment) [59].

C) Estradiol Cypionate

1) Therapeutic

a) Physical Findings

1) Female Hypogonadism

a) Estrogen administration and dosage should be guided by individual patient clinical response rather than by hormone levels when treating female hypogonadism [55].

2) Postmenopausal Vasomotor Symptoms

a) Estrogen administration and dosage should be guided by individual patient clinical response rather than by hormone levels when treating postmenopausal vasomotor symptoms [55].

2) Toxic

a) Laboratory Parameters

1) Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding [55].

2) Serum calcium should be monitored in patients with preexisting severe hypocalcemia or in patients with breast cancer and bone metastases [55].

3) Plasma triglycerides should monitored in patients with preexisting hypertriglyceridemia [55].

4) Thyroid function should be monitored in patients with preexisting hypothyroidism in order to maintain free thyroid hormone levels in an appropriate range [55].

b) Physical Findings

1) All women should receive yearly breast examinations by a healthcare provider and should perform self-examinations of the breasts every month. Mammography examinations should be

scheduled based on patient age, risk factors, and prior mammogram results [55].

2) An eye examination should be scheduled if there is a sudden partial or complete loss of vision or a sudden onset of proptosis, diplopia, or migraine. Estrogens should be discontinued pending examination and discontinued permanently if examination reveals papilledema or retinal vascular lesions [55].

3) Blood pressure should be monitored at regular intervals during estrogen use [55].

4) Patients with conditions that may be influenced by fluid retention such as cardiac or renal dysfunction should be carefully observed for exacerbation of their condition [55].

D) Estradiol Valerate

1) Therapeutic

a) Laboratory Parameters

1) Hypoestrogenism due to Hypogonadism, Castration or Primary Ovarian Failure

a) Estrogen administration and dosage should be guided by clinical response rather than by serum hormone levels (estradiol, follicle stimulating hormone) [57].

2) Postmenopausal Vasomotor Symptoms

a) Estrogen administration and dosage should be guided by clinical response rather than by serum hormone levels (estradiol, follicle stimulating hormone) [57].

3) Postmenopausal Vulvar and Vaginal Atrophy

a) Estrogen administration and dosage should be guided by clinical response rather than by serum hormone levels (estradiol, follicle stimulating hormone) [57].

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2) Toxic

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1) Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding [57].

2) Serum calcium should be monitored in patients with pre-existing severe hypocalcemia or in patients with breast cancer and bone metastases [57].

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b) Physical Findings

1) All women should receive yearly breast examinations by a healthcare provider and should perform self-examinations of the breasts every month. Mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results [57].

2) An eye examination should be scheduled if there is a sudden partial or complete loss of vision or a sudden onset of proptosis, diplopia, or migraine. Estrogens should be discontinued pending examination and discontinued permanently if examination reveals papilledema or retinal vascular lesions [57].

3) Blood pressure should be monitored at regular intervals during estrogen use [57].

4) Patients with conditions that may be influenced by fluid retention such as cardiac or renal dysfunction should be carefully observed for exacerbation of their condition [57].

5) Periodic monitoring of bone maturation and effects on epiphyseal centers is recommended when estrogen is administered to patients whose bone growth is not complete [57].

Do Not Confuse

No results available

MECHANISM OF ACTION

Mechanism of Action

A) Estradiol

1) Estrogens bind to nuclear receptors in estrogen-responsive tissues. Estrogens modulate the pituitary secretion of the gonadotropins, luteinizing hormone and follicle stimulating hormone through a negative feedback mechanism. Estrogens reduce the elevated levels of these hormones in postmenopausal women [7][13][38][35][8][92][9][11][12][36][14][15][94].

2) Estrogens are important for developing and maintaining the female reproductive system and secondary sex characteristics. Estrogens promote growth and development of the vagina, uterus, and fallopian tubes, and enlargement of the breasts. Indirectly, they stimulate and limit linear skeletal growth. Estrogens have wide-spread effects on metabolism such as transporting of proteins and electrolyte balance [114][509].

3) Estrogens are necessary for maintaining the normal menstrual cycle. During the follicular phase of the menstrual cycle, when estrogen levels are high, there is a proliferation of the vaginal and uterine mucosa and increased cervical secretions. As estrogen levels decline at the end of the cycle, menstruation begins [505][510]; (Naftolin & Tolis, 1978).

4) In non-pregnant women, estrogens (and progesterone) support the physiologic processes resulting in ovulation and preparation of the uterine endometrium to support conception. At the time of menopause, ovarian follicles are incapable of responding to gonadotropin stimulation with progressive maturation. The ovaries cease to produce estrogens and progesterone, and gonadotropin levels rise dramatically as androgen and estrogen levels decrease. Menopause is clinically defined as a duration of amenorrhea of 6 to 12 months in a woman over 45 years of age [511]. In the premenopausal period, estradiol secretion from the ovaries is the major source of estrogen production. Extraglandular production of estrone occurs from androstenedione, derived from both the adrenals and ovaries. In the menopause, ovarian estradiol production diminishes and a peripheral conversion of adrenal androstenedione to estrone becomes the principle source of estrogen [512].

5) All estrogens act similarly and there is no evidence that there are biological differences among various estrogen preparations, other than their ability to bind to receptors once inside target cells. There is no evidence that one estrogen is more carcinogenic than another or that one preparation is safer than another. Differences among various estrogens primarily arise from the dose administered and relative potency (Schiff and Ryan, 1980). All estrogens exert their primary effects on the interphase DNA-protein complex (chromatin) by binding to a receptor usually located in the cytoplasm of a target cell and initiation of translocation of the hormone-receptor complex to the nucleus [513]. The specificity of estrogen action depends upon the presence and concentration of "estrogen targets", which are defined as tissues containing a high concentration of estrogen receptors. These include the endometrium, myometrium, oviduct, vagina, fallopian tube, cervix, brain, liver, placenta, ovarian cells and Leydig's cell. Other tissues reportedly containing estrogen receptors include kidney, prostate, pancreas, heart and skin [513].

6) In breast tissue, estrogens stimulate the growth and differentiation of the ductal epithelium, induce mitotic activity of ductal cylindric cells, and stimulate the growth of connective tissue. In addition, estrogens exert histamine-like effects on the microcirculation of the breast and stimulate the growth of breast cancer cells [514].

7) The mechanism by which estrogens prevent postmenopausal bone loss is not clear. Estrogens cause a clear decrease in calcium excretion and result in a calcium balance indistinguishable from normal premenopausal women [515][516][97]. Though the precise mechanism remains unknown, changes in vitamin D metabolism (increased 1-hydroxylation of 25-OH-D) as well as increased levels of serum calcitonin have been implicated [517][518]; (Taggart et al, 1982). One study has also shown that estrogen therapy reduces the sensitivity of postmenopausal osteoporotic bone to the resorptive effects of parathyroid hormone [519]. Further study is needed.

B) Estradiol Acetate

1) Estrogens bind to nuclear receptors in estrogen-responsive tissues. Estrogens modulate the pituitary secretion of the gonadotropins, luteinizing hormone and follicle stimulating hormone through a negative feedback mechanism. Estrogens reduce the elevated levels of these hormones in postmenopausal women [170][60].

2) Estrogens are important for developing and maintaining the female reproductive system and secondary sex characteristics. Estrogens promote growth and development of the vagina, uterus, and fallopian tubes, and enlargement of the breasts. Indirectly, they stimulate and limit linear skeletal growth. Estrogens have wide-spread effects on metabolism such as transporting of proteins and electrolyte balance [114][509].

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C) Estradiol Cypionate

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PHARMACOKINETICS

Pharmacokinetics

Onset and Duration

A) Onset

1) Estradiol

a) Initial Response

1) Oral

a) Estrogen replacement: 3 days [9].

1) On the third consecutive day of dosing, the mean serum concentration of estradiol and estrone increased to 59 and 302 picograms/milliliter (pg/mL) above baseline, respectively,

after oral estradiol 2 milligrams daily were administered to postmenopausal women [9].

b) Menopausal symptoms: 2 to 4 weeks [500][501]

1) Time to significant improvement of menopausal symptoms relative to baseline was 2 to 4 weeks [500][501].

2) Transdermal

a) Estrogen replacement: 4 hours [9][11][12]

1) After a single application of estradiol transdermal patches that provided 0.05 and 0.1 milligrams of estradiol per day, blood levels of estradiol were increased within 4 hours after administration [9].

2) Following application to the abdomen of estradiol transdermal patches that provided 0.0375 and 0.1 milligrams (mg) of estradiol per day and application to the buttocks of estradiol transdermal patches that provided 0.1 mg of estradiol per day, estradiol levels were increased above baseline within 4 hours after administration [11][12].

2) Estradiol Cypionate

a) Initial Response

1) Menopausal vasomotor symptoms, intramuscular: 1 to 5 days [55].

a) Comparative clinical trials have demonstrated that relief of vasomotor symptoms in menopausal women occurs approximately within 1 to 5 days after a single intramuscular injection of estradiol cypionate 5 milligrams [55].

B) Duration

1) Estradiol

a) Single Dose

1) Transdermal

a) Estrogen replacement: within 24 hours [9]

1) After a single application of estradiol transdermal patches that provided 0.05 and 0.1 milligrams of estradiol per day, mean serum estradiol concentrations of 32 and 67 picograms/milliliter (pg/mL), respectively, were maintained above baseline over the application period. Serum concentration levels of estrone averaged 9 and 27 pg/mL above baseline, respectively. Serum concentrations of estradiol and estrone returned to preapplication levels within 24 hours after removal of the patch [9].

b) Multiple Dose

1) Transdermal

a) Estrogen replacement: 12 to 24 hours [11][12]

1) In a multiple-dose study involving 17 healthy postmenopausal women, estradiol transdermal systems were applied to the abdomen at a dose of 0.05 and 0.1 milligrams (mg)/day) or to the buttocks at a dose of 0.1 mg/day. Plasma concentrations of estradiol and estrone remained slightly above baseline at 12 hours after removal of the transdermal systems. In another study, the levels return to baseline values with 24 hours after the patch removal [11][12].

2) Estradiol Cypionate

a) Single Dose

1) Menopausal vasomotor symptoms, intramuscular: average of 5 weeks [55].

a) Comparative clinical trials have demonstrated that relief of vasomotor symptoms in menopausal women was maintained for 1 to 8 weeks (average 5 weeks) after a single intramuscular injection of estradiol cypionate 5 milligrams [55].

2) Vaginal estrogenic effect, intramuscular: 3 to 4 weeks [55]

a) Comparative clinical trials have demonstrated that after a single intramuscular injection of estradiol cypionate 5 milligrams, the average duration of estrogenic effect, as measured by vaginal smear, was approximately 3 to 4 weeks [55].

Drug Concentration Levels

A) Estradiol

1) Therapeutic Drug Concentration

a) Transdermal Gel

1) Estrogel(R): 28.3 picograms/mL [13]

a) By day 14, the time-averaged serum estradiol and estrone concentrations over the 24-hour dose interval after administration of 1.25 grams estradiol topical gel to one arm were 28.3 and 48.6 picograms/milliliter, respectively. The serum concentrations of estradiol reached steady state after the third daily application of 2.5 grams topical estradiol gel (1.25 grams applied to each arm) [13].

2) Divigel(R): 9.8, 21, 30.5 picograms/mL (0.25, 0.5, and 1 mg daily dose, respectively) [38]

a) The steady state serum concentration of estradiol is achieved by day 12 following daily application of estradiol topical gel 0.1% to the skin of the upper thigh. The mean serum estradiol levels on day 14 after multiple daily doses of estradiol topical gel delivering 0.25 milligram was 9.8 picograms/milliliter (pg/mL). The mean steady state serum concentration of estradiol after multiple daily doses of estradiol topical gel 0.5 milligram was 21 pg/mL. The mean steady state serum concentration of estradiol after multiple daily doses of estradiol topical gel 1 milligram was 30.5 pg/mL[38].

b) Transdermal Patch

1) Alora(R)

a) The average base-line adjusted steady state concentrations of estradiol during a 2 year, randomized, double-blind, controlled trial involving 355 hysterectomized women were 18.6, 35.9, and 50.1 picograms/milliliter for the 0.025, 0.05, and 0.075 milligrams/day dose, respectively [8].

The mean steady state serum concentrations of estradiol after administration of Alora(R) patches are presented below. Studies 1 and 2 were of 3 months duration and Study 3 was of 2 years duration [8]:

Dose (milligrams/day)	Study 1 (pg/mL)	Study 2 (pg/mL)	Study 3 (pg/mL)
0.025	--	--	24.5
0.05	46.9	38.8	42.6
0.075	--	--	56.7
0.1	99.2	97.0	--
pg/mL: picogram/milliliter			

2) Estraderm(R)

a) Steady state serum estradiol levels of 30 picograms/mL and estrone levels of 12 picograms/mL were reported in a 3-week multiple-application study (n=14) receiving Estraderm(R) 0.05 twice a week [9].

3) Vivelle(R) and Vivelle-Dot(R)

a) The mean steady state plasma concentrations of estradiol after administration of Vivelle(R) are summarized below [11][12]:

Dose (milligrams/day)	Application Site	Cavg (picograms/milliliter)
0.0375	Abdomen	34
0.05	Abdomen	57
0.075	Abdomen	72
0.1	Abdomen	89
0.1	Buttock	104
Cavg: average plasma concentration		

4) Transdermal Spray

a) Evamist(TM): 19.6, 30.7, and 30.9 picograms/mL (1, 2, or 3 sprays daily, respectively) [36]

1) By day 14, the mean steady state concentration of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of one 90 microliter (mcL) spray delivering 1.53 milligrams (mg) estradiol was 19.6 picograms/milliliter (pg/mL). The mean steady state concentration of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of two 90 mcL sprays delivering a total of 3.06 mg estradiol was 30.7 pg/mL. The mean steady state concentration of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of three 90 mcL sprays delivering a total of 4.59 mg estradiol was 30.9 pg/mL [36].

5) Vaginal Insert

a) Vaginal, insert (estradiol): 3.6 to 4.6 picograms/mL (pg/mL; Day 14) [5]

1) Following 14 days of once-daily administration in postmenopausal women (n=54), average 24-hour concentration of estradiol was 3.6 +/- 1.8 pg/mL with the 4-mcg insert and 4.6 +/- 2.3 pg/mL with the 10-mcg insert, compared with a placebo level of 4.3 +/- 2.8 mcg/mL [5].

b) Vaginal, insert (estrone): 13.6 to 19.3 picograms/mL (pg/mL; Day 14) [5]

1) Following 14 days of once-daily administration in postmenopausal women (n=54), average 24-hour concentration of estrone was 13.6 +/- 4.8 pg/mL with the 4-mcg insert and 19.3 +/- 10.2 pg/mL with the 10-mcg insert, compared with a placebo level of 17.8 +/- 7.5 mcg/mL [5].

6) Vaginal Ring

a) The steady state concentration values at 48 hours, 4 weeks, and 12 weeks for estradiol and estrone, as well as baseline-adjusted estradiol and estrone following a single estradiol vaginal ring application in 14 healthy postmenopausal women are summarized below [15]:

	Css-48 hr (picograms/milliliter)	Css-4w (picograms/milliliter)	Css-12w (picograms/milliliter
Estradiol	11.2	9.5	8.0
Baseline-adjusted Estradiol	3.6	2	0.4
Estrone	52.5	43.8	47.0
Baseline-adjusted Estrone	6.2	-2.4	0.8
Css: Steady state serum concentration; hr: hours; w: week			

b) The mean steady state serum estradiol concentrations after 1 to 4 estradiol vaginal rings (delivering 2 milligrams estradiol per ring) were inserted at three month intervals during a phase II study involving 222 postmenopausal women were 7.8, 7.0, 7.0, and 8.1 picograms/milliliter at 12, 24, 36, and 48 weeks, respectively. Similar results were seen in estrone concentrations [15].

2) Peak Concentration

a) Transdermal Gel

1) Estrogel(R): 46.4 picograms/mL (1.25 g daily) [13]

a) The mean Cmax of estradiol on day 14 was 46.4 picograms/milliliter after estradiol topical gel 1.25 grams was administered to 24 postmenopausal women once daily on the posterior surface of the arm from wrist to shoulder for 14 days. The mean Cmax of estrone was 64.2 picograms/milliliter [13].

2) Divigel(R): 14.7, 28.4, and 51.5 picograms/mL (0.25, 0.5, and 1.0 mg daily) [38]

a) In postmenopausal women, the mean Cmax of estradiol after multiple daily doses of estradiol topical gel delivering 0.25 milligram was 14.7 picograms/milliliter (pg/mL). The mean Cmax of estradiol after multiple daily doses of estradiol topical gel 0.5 milligram was 28.4 pg/mL. The mean Cmax of estradiol after multiple daily doses of estradiol topical gel 1 milligram was 51.5 pg/mL[38].

b) Transdermal Patch

1) Alora(R): 92 to 144 picograms/mL [8]

The mean Cmax of Alora(R) over an 84-hour dosing interval is presented below (* denotes Cmax for hip was statistically different from Cmax for abdomen) [8]:

Dose (milligrams/day)	Application Site	N	Dosing	Cmax (picograms/milliliter)
0.05	Abdomen	20	Multiple	92
0.075	Abdomen	20	Multiple	120
0.1	Abdomen	42	Multiple	144
0.05	Abdomen	31	Single	53
0.05	Buttock	31	Single	67
0.05	Hip*	31	Single	69
Cmax: Peak serum concentrations				

2) Climara(R): 32 to 174 picograms/mL [92]

a) The average Cmax of estradiol during a 3-week multiple application study in which 24 postmenopausal women wore the 25 square centimeter (cm(2)) Climara(R) system was 100 picograms/milliliter (pg/mL). Serum estrone Cmax level was 60 pg/mL [92].

b) In a single dose study in which 38 postmenopausal women wore a 25 square centimeter (cm(2)) Climara(R) system for one week either on the abdomen or buttocks, the serum Cmax for estradiol was 25% higher with the buttock application than with the abdomen application [92].

A summary of calculated Cmax values for estradiol during evaluation of Climara(R) is outlined in the following table [92]:

Delivery Rate (milligrams/day)	Surface Area (square centimeters)	Application Site	N	Dosing	Cmax (picograms/milliliter)
0.025	6.5	Abdomen	24	Single	32
0.05	12.5	Abdomen	102	Single	71
0.1	25	Abdomen	139	Single	147
0.1	25	Buttock	38	Single	174

3) Vivelle(R), Vivelle-Dot(R): 46 to 145 picograms/mL [11][12]

The mean plasma Cmax values of estradiol after administration of Vivelle(R) at steady state are summarized below [11][12]:

Dose (milligrams/day)	Application Site	Cmax (picograms/milliliter)
0.0375	Abdomen	46
0.05	Abdomen	83
0.075	Abdomen	99
0.1	Abdomen	133
0.1	Buttock	145
Cmax: Peak plasma concentration		

c) Transdermal Spray

1) Evamist(TM): 36.4, 57.4, and 54.1 picograms/mL (1, 2, or 3 sprays daily, respectively) [36]

a) By day 14, the mean Cmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of one 90 microliter (mcL) spray delivering 1.53 milligrams (mg) estradiol was 36.4 picograms/milliliter (pg/mL). The mean Cmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of two 90 mcL sprays delivering a total of 3.06 mg estradiol was 57.4 pg/mL. The mean Cmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of three 90 mcL sprays delivering a total of 4.59 mg estradiol was 54.1 pg/mL [36].

d) Vaginal Ring

1) The Cmax values for estradiol and estrone, as well as baseline-adjusted estradiol and estrone following a single estradiol vaginal ring application in 14 healthy postmenopausal women are summarized below:

	Cmax in picograms/milliliter
Estradiol	63.2
Baseline-adjusted Estradiol	55.6
Estrone	66.3
Baseline-adjusted Estrone	20
Cmax: Peak serum levels	

The initial estradiol Cmax after application of a second ring in the same women resulted in an approximate 38% lower Cmax, thought to be due to reduced systemic absorption via the treated vaginal epithelium [15].

e) Vaginal Insert

1) Vaginal, insert (estradiol): 4.8 to 7.3 picograms/mL (pg/mL; Day 14); 4.3 to 4.8 pg/mL (Day 84) [5]

a) Following 14 days of once-daily administration in postmenopausal women (n=54), mean Cmax of estradiol was 4.8 +/- 2.3 pg/mL with the 4-mcg insert and 7.3 +/- 2.4 pg/mL with the 10-mcg insert, compared with a placebo level of 5.5 +/- 3.4 mcg/mL. After Day 14, women received 1 insert twice weekly. At Day 84, estradiol concentrations compared to baseline concentrations were: 4.3 vs 3.9 pg/mL for 4 mcg; 4.8 vs 5 pg/mL for 10 mcg; and 4.4 vs 4.5 pg/mL for placebo [5].

2) Vaginal, insert (estrone): 16 to 23.9 picograms/mL (pg/mL; Day 14) [5]

a) Following 14 days of once-daily administration in postmenopausal women (n=54), mean Cmax of estrone was16 +/- 5.5 pg/mL with the 4-mcg insert and 23.9 +/- 13.4 pg/mL with the 10-mcg insert, compared with a placebo level of 22.8 +/- 10.9 mcg/mL [5].

f) Vaginal Tablets

1) Vaginal, tablets (estradiol): 47 to 51 picograms/mL [94]

a) During a double-blind, randomized trial, the mean Cmax of estradiol at day 1, 14, and 84 was 51, 47, and 49 picograms/milliliter, respectively, during administration of estradiol 25 mcg vaginal tablets over a 12-week period [94].

2) Vaginal, tablets (estrone): 35 to 39 picograms/mL [94]

a) During a double-blind, randomized trial, the mean Cmax of estrone at day 1, 14, and 84 was 35, 39, and 35 picograms/milliliter, respectively, during administration of estradiol 25 mcg vaginal tablets over a 12-week period [94].

3) Time to Peak Concentration

a) Transdermal Gel

1) Divigel(R): 16, 10, and 8 hr (0.25, 0.5, and 1 mg daily dose, respectively) [38]

a) In postmenopausal women, the median Tmax of estradiol after multiple daily doses of estradiol topical gel delivering 0.25 milligram was 16 hours. The median Tmax of estradiol after multiple daily doses of estradiol topical gel 0.5 milligram was 10 hours. The median Tmax of estradiol after multiple daily doses of estradiol topical gel 1 milligram was 8 hours [38].

b) Transdermal Spray

1) Evamist(TM): 20, 18, and 20 hr (1, 2, or 3 sprays daily, respectively) [36]

a) By day 14, the median Tmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of one 90 microliter (mcL) spray delivering 1.53 milligrams (mg) estradiol was 20 hours (hr). The median Tmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of two 90 mcL sprays delivering a total of 3.06 mg estradiol was 18 hr. The median Tmax of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of three 90 mcL sprays delivering a total of 4.59 mg estradiol was 20 hr [36].

c) Vaginal Ring

1) Estring(R): 0.5 to 1 hour [15]

a) The time to attain peak serum estradiol levels after insertion of estradiol vaginal ring during a phase 1 study involving 14 postmenopausal women was 0.5 to 1 hour [15].

4) Area Under the Curve

a) Transdermal

1) Divigel(R): 236, 504, and 732 picograms x hr/mL (0.25, 0.5, and 1.0 mg daily dose, respectively) [38]

a) In postmenopausal women, the mean AUC of estradiol after multiple daily doses of estradiol topical gel delivering 0.25 milligram was 236 picograms x hour/milliliter (pg x hr/mL), respectively. The mean AUC of estradiol after multiple daily doses of estradiol topical gel 0.5 milligram was 504 pg x hr/mL. The mean AUC of estradiol after multiple daily doses of estradiol topical gel 1.0 milligram was 732 pg x hr/mL[38].

2) Evamist(TM): 471, 736, and 742 pg x hr/mL (1, 2, or 3 sprays daily dose, respectively) [36]

a) By day 14, the mean AUC of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of one 90 microliter (mcL) spray delivering 1.53 milligrams (mg) estradiol was 471 picograms x hour/milliliter (pg x hr/mL). The mean AUC of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of two 90 mcL sprays delivering a total of 3.06 mg estradiol was 736 pg x hr/mL. The mean AUC of estradiol after multiple daily doses of estradiol transdermal spray was administered at a dose of three 90 mcL sprays delivering a total of 4.59 mg estradiol was 742 pg x hr/mL [36].

b) Vaginal

1) Vaginal, tablets (estradiol): 538 to 567 picograms x hr/mL [94]

a) During a double-blind, randomized trial, the mean AUC of estradiol at day 1, 14, and 84 was 538, 567, and 563 picograms x hour/milliliter, respectively, during administration of estradiol 25 mcg vaginal tablets over a 12-week period [94].

2) Vaginal, tablets (estrone): 649 to 744 picograms x hr/mL [94]

a) During a double-blind, randomized trial, the mean AUC of estrone at day 1, 14, and 84 was 649, 744, and 681 picograms x hour/milliliter, respectively, during administration of estradiol 25 mcg vaginal tablets over a 12-week period [94].

B) Estradiol Acetate

1) Peak Concentration

a) Oral: estradiol, 56.7, 90.1, and 177.3 pg/mL (0.45, 0.9, and 1.8 mg daily) [170]

b) Oral: baseline adjusted estrone, 155.0, 313.9, and 680.6 pg/mL (0.45, 0.9, and 1.8 mg daily) [170]

1) In 18 healthy postmenopausal women, the mean Cmax of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.45 milligrams was 56.7 and 155.0 picograms/milliliter (pg/mL), respectively. The mean Cmax of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.9 milligrams was 90.1 and 313.9 pg/mL, respectively. The mean Cmax of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 1.8 milligrams was 177.3 and 680.6 pg/mL, respectively [170].

c) Vaginal, ring: estradiol, 1129 to 1665 pg/mL (0.05 mg/day) [60]

d) Vaginal, ring: estrone, 141 pg/mL (0.05 mg/day) [60]

e) Vaginal, ring: estrone sulfate, 2365 pg/mL (0.05 mg/day) [60]

1) The mean Cmax of estradiol, estrone, and estrone sulfate after administration of estradiol acetate vaginal ring which delivered 0.05 milligram/day (mg/day) of estradiol was 1129 to 1665, 141, and 2365 picograms/milliliter (pg/mL) [60].

2) Time to Peak Concentration

a) Oral: estradiol, 0.43 to 0.75 hr [170]

b) Oral: baseline adjusted estrone, 5.0 to 6.0 hr [170]

1) In 18 healthy postmenopausal women, the median Tmax of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.45 milligrams was 0.50 and 6.0 hours, respectively. The median Tmax of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.9 milligrams was 0.43 and 5.0 hours, respectively. The median Tmax of estradiol and baseline-adjusted estrone

after multiple-dose administration of oral estradiol acetate 1.8 milligrams was 0.75 and 6.0 hours, respectively [170].

c) Vaginal, ring: estradiol, 0.7 to 0.9 hr [60]

d) Vaginal, ring: estrone, 6.2 hr [60]

e) Vaginal, ring: estrone sulfate, 9.3 hr [60]

1) The mean Tmax of estradiol, estrone, and estrone sulfate after administration of estradiol acetate vaginal ring which delivered 0.05 milligram/day (mg/day) of estradiol was 0.7 to 0.9, 6.2, and 9.3 hours [60].

3) Area Under the Curve

a) Oral: estradiol, 565.0, 1066.5, and 2211.3 pg x hr/mL (0.45, 0.9, and 1.8 mg daily) [170]

b) Oral: baseline adjusted estrone, 2363.8, 4980.9, and 11510.8 pg x hr/mL (0.45, 0.9, and 1.8 mg daily) [170]

1) In 18 healthy postmenopausal women, the mean AUC of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.45 milligrams was 565.0 and 2363.8 picograms x hour/milliliter (pg x hr/mL), respectively. The mean AUC of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.9 milligrams was 1066.5 and 4980.9 pg x hr/mL, respectively. The mean AUC of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 1.8 milligrams was 2211.3 and 11510.8 pg x hr/mL, respectively [170].

ADME

Absorption

A) Estradiol

1) Bioavailability

a) Transdermal

1) Transdermal, patch: 20 times higher than oral [92][9]

a) The systemic availability of estradiol after transdermal administration is approximately 20 times greater than that after oral administration due to the lack of first pass metabolism during transdermal administration [92][9].

b) Vaginal

1) Vaginal ring: approximately 8% [15]

a) Approximately 8% (95% confidence interval: 2.8 - 12.8%) of the daily amount release locally from Estring(R) was absorbed systemically unchanged in postmenopausal women [15].

2) Transdermal

a) Emulsion: exposure increased by sunscreen use [35]

1) The exposure to estradiol is increased by approximately 35% when sunscreen is applied 10 and 25 minutes prior to application of estradiol emulsion, and by 15% when sunscreen is applied 25 minutes after the application of the estradiol emulsion [35].

b) Gel: passive diffusion [13][38]

1) Estradiol gel is absorbed via a passive diffusion process with the rate of diffusion across the stratum corneum being the rate-limiting factor [13][38].

c) Patch: passive diffusion [8]

1) Estradiol, when administered as a transdermal patch, is absorbed via a passive diffusion process with the rate of diffusion across the stratum corneum being the rate-limiting factor [8].

2) The average daily absorbed dose of estradiol after transdermal estradiol systems (Alora(R)) were worn over a continuous four day interval during 251 separate occasions (n=123) was 0.003 milligrams per square centimeter (cm(2)) active surface area. The nominal mean in vivo daily delivery rates of estradiol from the 9, 18, 27, and 36 cm(2) systems were 0.027, 0.054, 0.081, and 0.11 milligrams/day, respectively [8].

3) Vaginal

a) Ring: rapid for first hour; declines to constant rate for the remaining 3 months [15].

1) Absorption from estradiol occurs rapidly for the first hour but then declines to a steady rate for the remainder of the 3-month dosing interval. Estradiol is rapidly absorbed through the vaginal mucosa [60][15].

B) Estradiol Acetate

1) Bioavailability

a) Oral, rapidly absorbed [170].

1) Estradiol was rapidly absorbed following administration of oral estradiol acetate [170].

b) Vaginal, rapid for first hour; declines to constant rate for the remaining 3 months [60].

1) Absorption from estradiol acetate occurs rapidly for the first hour but then declines to a steady rate for the remainder of the 3-month dosing interval. Estradiol acetate and estradiol are both rapidly absorbed through the vaginal mucosa [60].

2) Effects of Food

a) Oral, no effect on systemic availability [170]

1) Compared to the fasted state, the Cmax of estradiol following administration of 1.8 milligrams oral estradiol acetate was decreased by 36% when given with food. However, the AUC was comparable between the fed and fasted states [170].

C) Estradiol Cypionate

1) Bioavailability

a) Intramuscular, absorbed over several weeks [55].

1) When conjugated with aryl and alkyl groups for parenteral administration, the rate of absorption of estradiol cypionate as an oily preparation is slowed. A single intramuscular injection is absorbed over several weeks [55].

D) Estradiol Valerate

1) Bioavailability

a) Intramuscular, absorbed over several weeks [57].

1) When conjugated with aryl and alkyl groups for parenteral administration, the rate of absorption of estradiol cypionate as an oily preparation is slowed. A single intramuscular injection is absorbed over several weeks [57].

Distribution

A) Distribution Sites

1) Estradiol

a) Protein Binding

1) Estrogens circulate in the blood bound primarily bound to sex hormone binding globulin (SHBG) and to albumin [7][13][38][35][8][92][11][12][36][14][15][94].

2) Estradiol Acetate

a) Protein Binding

1) Estrogens circulate in the blood bound primarily bound to sex hormone binding globulin (SHBG) and to albumin [170][60].

3) Estradiol Cypionate

a) Protein Binding

1) Estrogens circulate in the blood bound primarily to sex hormone binding globulin (SHBG) and to albumin [55].

4) Estradiol Valerate

a) Protein Binding

1) Estrogens circulate in the blood bound primarily to sex hormone binding globulin (SHBG) and to albumin [57].

B) Distribution Kinetics

1) Estradiol

a) Volume of Distribution

1) The distribution of exogenous and endogenous estrogens is similar. Estrogens are widely distributed in the body and are found in higher concentrations in the sex hormone target organs [7][13][38][35][8][92][11][12][36][14][15][94].

2) Estradiol Acetate

a) Volume of Distribution

1) The distribution of exogenous and endogenous estrogens is similar. Estrogens are widely distributed in the body and are found in higher concentrations in the sex hormone target organs [170][60].

3) Estradiol Cypionate

a) Volume of Distribution

1) The distribution of exogenous and endogenous estrogens is similar. Estrogens are widely distributed in the body and are found in higher concentrations in the sex hormone target organs [55].

4) Estradiol Valerate

a) Volume of Distribution

1) The distribution of exogenous and endogenous estrogens is similar. Estrogens are widely distributed in the body and are found in higher concentrations in the sex

hormone target organs [57].

Metabolism

A) Metabolism Sites and Kinetics

1) Estradiol

a) Liver, primary [7][13][38][35][8][92][9][11][12][36][14][15][94]

1) Exogenous estrogens, like endogenous estrogens, are transformed in the liver. Estradiol acetate is hydrolyzed to estradiol. Estradiol is converted reversibly to estrone and both can be converted to estriol, the major urinary metabolite. Additionally, estrogens undergo enterohepatic recirculation via sulfate and glucuronide conjugation in the liver, biliary secretion of conjugates into the intestine, and hydrolysis in the gut which is followed by reabsorption. A significant proportion of the circulating estrogens in postmenopausal women exists as sulfate conjugates, especially estrone sulfate [7][13][38][35][8][92][9][11][12][36][14][15][94].

2) Orally administered estradiol is rapidly metabolized in the liver to estrone and its conjugates which contributes to higher circulating levels of estrone than estradiol [8][9][11][12].

3) In vitro and in vivo studies indicate that estrogens are partially metabolized by cytochrome P450 3A4 [7][13][38][35][8][92][9][11][12][36][14][15].

4) Estradiol from the transdermal gel preparations does not undergo first pass metabolism and provides estradiol/estrone ratios at steady state in the range of 0.42 to 0.65 [13][38].

5) Vaginal delivery of estradiol does not undergo first pass metabolism [15][94].

b) Skin, small extent [8][9][11][12]

1) Transdermal estradiol is metabolized by the skin to a small extent. Transdermal administration produces therapeutic plasma levels of estradiol with lower levels of estrone and estrone conjugates. Therefore, smaller total doses are required for transdermal administration of estradiol compared with oral administration of estradiol [8][9][11][12].

2) Estradiol Acetate

a) Liver, primary [170][60]

1) Exogenous estrogens, like endogenous estrogens, are transformed in the liver. Estradiol acetate is hydrolyzed to estradiol. Estradiol is converted reversibly to estrone and both can be converted to estriol, the major urinary metabolite. Additionally, estrogens undergo enterohepatic recirculation via sulfate and glucuronide conjugation in the liver, biliary secretion of conjugates into the intestine, and hydrolysis in the gut which is followed by reabsorption. A significant proportion of the circulating estrogens in postmenopausal women exists as sulfate conjugates, especially estrone sulfate [170][60].

2) In vitro and in vivo studies indicate that estrogens are partially metabolized by cytochrome P450 3A4 [170][60].

3) Estradiol Cypionate

a) Liver, primary [55]

1) Exogenous estrogens, like endogenous estrogens, are transformed in the liver. Estradiol acetate is hydrolyzed to estradiol. Estradiol is converted reversibly to estrone and both can be converted to estriol, the major urinary metabolite. Additionally, estrogens undergo enterohepatic recirculation via sulfate and glucuronide conjugation in the liver, biliary secretion of conjugates into the intestine, and hydrolysis in the gut which is followed by reabsorption. A significant proportion of the circulating estrogens in postmenopausal women exists as sulfate conjugates, especially estrone sulfate [55].

2) In vitro and in vivo studies indicate that estrogens are partially metabolized by cytochrome P450 3A4 [55].

4) Estradiol Valerate

a) Liver, primary [57]

1) Exogenous estrogens, like endogenous estrogens, are transformed in the liver. Estradiol is converted reversibly to estrone and both can be converted to estriol, the major urinary metabolite. Additionally, estrogens undergo enterohepatic recirculation via sulfate and glucuronide conjugation in the liver, biliary secretion of conjugates into the intestine, and hydrolysis in the gut which is followed by reabsorption. A significant proportion of the circulating estrogens in postmenopausal women exists as sulfate conjugates, especially estrone sulfate [57].

2) In vitro and in vivo studies indicate that estrogens are partially metabolized by cytochrome P450 3A4 [57].

B) Metabolites

1) Estradiol

a) Estradiol, active [7][13][38][35][8][92][9][11][12][36][14][15][94]

1) Estradiol is the principal intracellular human estrogen and is substantially more potent at the receptor site than its metabolites, estrone and estriol [7][13][38][35][8][92][9][36][14][15][94].

b) Estrone, active [7][13][38][35][8][92][9][36][14][15][94]

c) Estriol, active[7][13][38][35][8][92][9][36][14][15][94]

2) Estradiol Acetate

a) Estradiol, active [170][60]

1) Estradiol is the principal intracellular human estrogen and is substantially more potent at the receptor site than its metabolites, estrone and estriol [170][60].

b) Estrone, active [170][60]

c) Estriol, active[170][60]

3) Estradiol Cypionate

a) Estrone, active [55]

b) Estriol, active[55]

c) Estradiol is the principal intracellular human estrogen and is substantially more potent at the receptor site than its metabolites, estrone and estriol [55].

4) Estradiol Valerate

a) Estrone, active [57]

b) Estriol, active[57]

c) Estradiol is the principal intracellular human estrogen and is substantially more potent at the receptor site than its metabolites, estrone and estriol [57].

Excretion

A) Kidney

1) Estradiol

a) Renal Clearance (rate)

1) Transdermal

a) Transdermal, patch (Alora(R)): 53 to 69 L/hr [8]

The mean clearance of Alora(R) over an 84-hour dosing interval is presented below [8]:

Dose (milligrams/day)	Application Site	N	Dosing	Clearance (liters/hour)
0.05	Abdomen	20	Multiple	54
0.075	Abdomen	20	Multiple	53
0.1	Abdomen	42	Multiple	61
0.05	Abdomen	31	Single	69
0.05	Buttock	31	Single	66
0.05	Hip*	31	Single	62

b) Renal Excretion (%)

1) 5% to 8% unchanged [15]

a) At 4 and 12 weeks after application of estradiol vaginal ring, the mean percent dose that was excreted in the urine as estradiol was 5% and 8%, respectively [15].

2) Estradiol, estrone, and estriol, as well as their glucuronide and sulfate conjugates, are excreted in urine [7][13][38][35][8][92][9][11][12][36][14][15][94].

2) Estradiol Acetate

a) Renal Excretion (%)

1) Estradiol, estrone, and estriol, as well as their glucuronide and sulfate conjugates, are excreted in urine [170][60].

3) Estradiol Cypionate

a) Renal Excretion (%)

1) Estradiol, estrone, and estriol, as well as their glucuronide and sulfate conjugates, are excreted in urine [55].

4) Estradiol Valerate

a) Renal Excretion (%)

1) Estradiol, estrone, and estriol, as well as their glucuronide and sulfate conjugates, are excreted in urine [57].

B) Bile

1) Estradiol

a) Estrogens undergo biliary secretion of conjugates into the intestine [7][13][38][35][8][92][9][11][12][36][14][15][94][502][503][504][505][114][506][507].

2) Estradiol Acetate

a) Estrogens undergo biliary secretion of conjugates into the intestine [170][60][502][503][504][505][114][506][507].

3) Estradiol Cypionate

a) Estrogens undergo biliary secretion of conjugates into the intestine, hydrolyzed and reabsorbed [55][502][503][504][505][114][506][507].

4) Estradiol Valerate

a) Estrogens undergo biliary secretion of conjugates into the intestine, hydrolyzed and reabsorbed [57][502][503][504][505][114][506][507].

Elimination Half-life

A) Parent Compound

1) Transdermal Gel

a) Estrogel(R): 36 hours [13][38]

1) The apparent terminal half-life for estradiol was 36 hours following administration of 1.25 g of Estrogel(R) and 36 hours [13].

b) Divigel(R): 10 hours [38]

1) The apparent terminal half-life of Divigel(R) was about 10 hours [38].

2) Transdermal Patch

a) Alora(R): 1.75 hours [8]

1) The apparent mean serum half-life of estradiol when administered as the Alora(R) transdermal patch was 1.75 +/- 2.87 hours [8].

b) Vivelle(R): 4.4 hours [11]

c) Vivelle-Dot(R): 5.9 to 7.7 hours [12]

B) Metabolites

1) Estradiol Acetate

a) Oral: estradiol, 21.4 hr to 25.9 hr [170]

b) Oral: baseline adjusted estrone, 15.9 hr to 17.6 hr [170]

1) In 18 healthy postmenopausal women, the mean half-life of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.45 milligrams was 25.9 and 15.9 hours, respectively. The mean half-life of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 0.9 milligrams was 22.2 and 16.1 hours, respectively. The mean half-life of estradiol and baseline-adjusted estrone after multiple-dose administration of oral estradiol acetate 1.8 milligrams was 21.4 and 17.6 hours, respectively [170].

Extracorporeal Elimination

A) Hemodialysis

1) Dialyzable: Total serum estradiol concentrations are higher in postmenopausal women with end stage renal disease (ESRD) receiving maintenance hemodialysis at baseline and following oral doses of estradiol. Therefore, the traditional transdermal doses used in patients with normal renal function may be excessive for patients with ESRD who are receiving hemodialysis[92]

PATIENT EDUCATION

Medication Counseling

No results available

Patient Handouts

A) Estradiol (Absorbed through the skin)
Estradiol

Treats hot flashes and other symptoms of menopause or low estrogen.

When This Medicine Should Not Be Used:
This medicine is not right for everyone. Do not use it if you had an allergic reaction to estradiol, or if you have liver disease, breast cancer, or certain other types of cancer. Do not use it if you have a

history of blood clotting problems, or if you had a heart attack or stroke. Do not use this medicine if you may be pregnant, or if you have unusual vaginal bleeding that has not been checked by your doctor.

How to Use This Medicine:

Liquid Mixture, Gel/Jelly, Spray

Take your medicine as directed. Your dose may need to be changed several times to find what works best for you. This medicine is usually applied once a day, at the same time each day.
Use this medicine only on your skin. Rinse it off right away if it gets on a cut or scrape. Do not get the medicine in your eyes, nose, or mouth.
Read and follow the patient instructions that come with this medicine. Talk to your doctor or pharmacist if you have any questions.
Wash your hands with soap and water before and after you use this medicine.
To use the emulsion:

Apply the emulsion to your legs. The usual daily dose is 2 foil pouches, 1 for each leg.
Cut or tear open the first pouch at the notches near the top. Squeeze out all of the medicine from the pouch onto the top of your left thigh. Rub the medicine thoroughly into your thigh and calf, for about 3 minutes. Repeat these steps to apply the medicine in the second pouch to the right thigh and calf.
Allow the medicine to dry completely before you get dressed. Wait at least 25 minutes before you put on sunscreen.

To use the gel:

Gel pump: You get the correct dose of estradiol each time you press the pump. You may need to prime the pump by pumping 3 times (EstroGel®) or 10 times (Elestrin™) the first time you use it. Follow the patient instructions for the container you use. After you prime the pump, do not press the pump more than 1 time each time you use it.
Apply the gel to clean, dry, and unbroken skin. Spread the gel as thinly as possible over the entire area on the inside and outside of 1 arm from your wrist to your shoulder. Do not apply the medicine directly to your breasts or in or around your vagina.
Do not allow others to come in contact with the area of skin where you applied the gel for at least 1 hour after you use the medicine. Do not allow others to apply the gel for you. Allow the medicine to dry for at least 5 minutes before you get dressed.
Apply sunscreen at least 25 minutes after using Elestrin™ gel. Avoid applying sunscreen on the same application site for 7 days or more.
Gel packet: Cut or tear the Divigel® packet. Squeeze the packet contents onto your upper thigh. Gently spread the gel over your upper thigh, covering a space about the size of 2 palm prints. You do not need to massage or rub in the gel. Allow the gel to dry completely before you put on clothes. Alternate between your right and left upper thigh each day.
Do not allow others to come in contact with the area of skin where you applied the gel for at least 1 to 2 hours after you use the medicine. Do not allow others to apply the gel for you.

To use the spray:

The spray form comes in an applicator that delivers the same amount of estradiol with each spray. You need to prime the pump of a new spray applicator before you use it. Hold the spray upright and pump it 3 times. You only need to prime the pump the first time you use a new spray applicator.
Apply the medicine to clean, dry, and unbroken skin on the inside of your forearm between the elbow and the wrist. Do not apply the medicine directly to your breasts or in or around the vagina.
Allow the medicine to dry for at least 2 minutes before you get dressed. Wait at least 1 hour before you wash your skin.
If your doctor tells you to increase your dose, move the applicator to an area of the skin next to your previous application site before you apply the next dose. Do this for each spray.
Do not rub Evamist® spray into your skin.
Always place the protective cover back on the applicator.
Do not use the applicator for more than 56 sprays.
Apply sunscreen at least 1 hour before you apply Evamist®.

The estradiol gel and spray are flammable. Do not use these medicines near an open flame or while smoking.
Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.

Drugs and Foods to Avoid:

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

Some foods and medicines can affect how estradiol works. Tell your doctor if you are using St John's wort, carbamazepine, clarithromycin, erythromycin, itraconazole, ketoconazole, phenobarbital, rifampin, ritonavir, thyroid medicine, or a blood thinner (such as warfarin).
Do not put cosmetics or skin care products on the treated skin.
Do not eat grapefruit or drink grapefruit juice while you are using this medicine.

Warnings While Using This Medicine:

Pregnancy after menopause is not likely, but if you think you could be pregnant, tell your doctor. This medicine could harm an unborn baby.
Tell your doctor if you are breastfeeding, or if you have kidney disease, asthma, diabetes, edema (body swelling), endometriosis, epilepsy, migraine headaches, porphyria, lupus, thyroid problems, heart disease, high blood pressure, high cholesterol or triglycerides, inherited angioedema, or a history of cancer. Tell your doctor if you had liver problems caused by pregnancy or estrogen.
This medicine may cause the following problems:

Higher risk of heart attack, stroke, or blood clots
Higher risk of endometrial cancer, breast cancer, or uterine cancer
Gallbladder disease
Higher risk of dementia

Tell any doctor or dentist who treats you that you are using this medicine. This medicine may affect certain medical test results. You may need to stop using this medicine before you have surgery or if you need to stay in bed for a long time.
Your doctor will check your progress and the effects of this medicine at regular visits. Keep all appointments. You should have regular exams and mammograms as directed by your doctor.
Keep all medicine out of the reach of children. Never share your medicine with anyone.
Do not allow children or pets to touch the skin where you applied the medicine. If this happens, wash the child or pet's skin with soap and water.

Possible Side Effects While Using This Medicine:
Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing
Breast lumps
Chest pain, trouble breathing, or coughing up blood
Loss of vision, double vision, or other vision changes
Numbness or weakness on one side of your body, sudden or severe headache, problems with vision, speech, or walking
Sudden and severe stomach pain, with or without nausea, vomiting, fever, and lightheadedness
Swelling in your hands, ankles, or feet
Unusual vaginal bleeding or heavy bleeding

If you notice these less serious side effects, talk with your doctor:

Changes in weight or hair growth
Headache
Nausea, vomiting, or stomach cramps
Runny or stuffy nose, sore throat, or fever
Skin redness or itching where the medicine is applied
Swollen or tender breasts

If you notice other side effects that you think are caused by this medicine, tell your doctor.
B) Estradiol (By injection)
Estradiol

Treats hot flashes and other symptoms of menopause. Also treats prostate cancer in men, and treats lack of estrogen caused by a disorder of the ovaries in women.

When This Medicine Should Not Be Used:
You should not use this medicine if you have had an allergic reaction to hormone medicines. Do not use this medicine if you are pregnant, or if you have abnormal vaginal bleeding that has not been checked by a doctor. You should not use this medicine if you have a history of cancer of the breast, ovary, or uterus. Do not use if you have liver disease or a history of heart attack, stroke, or blood clots.

How to Use This Medicine:
Injectable

Your doctor will prescribe your exact dose and tell you how often it should be given. This medicine is given as a shot into one of your muscles. You may receive this medicine once a week, once every 2 weeks, or once every 4 weeks.
If you have not had your uterus removed (hysterectomy), you may need to use another hormone medicine together with estradiol. Carefully follow your doctor's instructions about all medicines you are using.
A nurse or other health provider will give you this medicine.
You may be taught how to give your medicine at home. Make sure you understand all instructions before giving yourself an injection. Do not use more medicine or use it more often than your doctor tells you to.
Read and follow the patient instructions that come with this medicine. Talk to your doctor or pharmacist if you have any questions.
Use a new needle and syringe each time you inject your medicine.

If a Dose is Missed:

Call your doctor or pharmacist for instructions.

How to Store and Dispose of This Medicine:

If you store this medicine at home, keep it at room temperature, away from heat and direct light. Do not allow the medicine to get cold.
Throw away used needles in a hard, closed container that the needles cannot poke through. Keep this container away from children and pets.
Ask your pharmacist, doctor, or health caregiver about the best way to dispose of any leftover medicine, containers, and other supplies. Throw away old medicine after the expiration date has passed.
Keep all medicine out of the reach of children. Never share your medicine with anyone.

Drugs and Foods to Avoid:

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

Warnings While Using This Medicine:

It is unlikely that you will become pregnant while you are going through menopause. But, you should know that using this medicine while you are pregnant could harm your unborn baby. If you think you have become pregnant while using the medicine, tell your doctor right away. If you have recently had an infant, tell your doctor if you are breast feeding.
Make sure your doctor knows if you have asthma, epilepsy, migraine headaches, heart disease, or kidney disease. Also tell your doctor if you have endometriosis, gallbladder disease, liver disease, lupus, porphyria, or an underactive thyroid.
This medicine should not be used to treat or prevent heart disease or stroke. In fact, hormone therapy can increase your risk of certain heart or blood vessel problems. Tell your doctor if you have a history of heart attack, stroke, high blood pressure, congestive heart failure, blood clots, or circulation problems.
Your risk of heart disease or stroke from this medicine is higher if you smoke. Your risk is also increased if you have diabetes or high cholesterol, or if you are overweight. Talk with your doctor about ways to stop smoking. If you have diabetes, keep it under control. Ask your doctor about diet and exercise to control your weight and blood cholesterol level.
This medicine may also increase your risk of other medical problems, including certain types of cancer. Talk with your doctor about how these risks might affect you.
Tell any doctor or dentist who treats you that you are using this medicine. You may need to stop using this medicine several days before you have surgery or medical tests. This medicine may also affect the results of certain medical tests.

Possible Side Effects While Using This Medicine:

Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing
Blistering, peeling, red skin rash.
Breast changes or lumps.
Chest pain, or coughing up blood.
Dark-colored urine or pale stools, yellowing of your skin or the whites of your eyes.
Nausea, vomiting, loss of appetite, pain in your upper stomach.
Numbness or weakness in your arm or leg, or on one side of your body.
Pain in your lower leg (calf).
Shortness of breath, cold sweat, and bluish-colored skin.
Sudden or severe headache, problems with vision, speech, or walking.
Swelling in your hands, ankles, or feet.
Vaginal bleeding or spotting.

If you notice these less serious side effects, talk with your doctor:

Joint pain.
Breast pain or tenderness, discharge from your nipples.
Hair loss, increased hair growth, or skin changes.
Mood changes or depression.
Problems or discomfort when wearing contact lenses.
Vaginal itching or discharge.
Weight gain or loss.

If you notice other side effects that you think are caused by this medicine, tell your doctor.

C) Estradiol (By mouth)

Estradiol

Treats symptoms caused by menopause or removal of the ovaries, and treats prostate or breast cancer. Also prevents osteoporosis.

When This Medicine Should Not Be Used:
You should not use this medicine if you have had an allergic reaction to estrogen medicines, if you are pregnant or breastfeeding, if you have had a blood clot, or if you have vaginal bleeding that has not been checked by a doctor. You should not use this medicine if you have had cancer of the uterus, or in certain cases of breast cancer.

How to Use This Medicine:
Tablet
Your doctor will tell you how much of this medicine to take and how often. Do not take more medicine or take it more often than your doctor tells you to.
You may take your medicine with food or milk to avoid stomach upset.

If a Dose is Missed:
If you miss a dose or forget to take your medicine, take it as soon as you can. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
Do not use extra medicine to make up for a missed dose.

How to Store and Dispose of This Medicine:
Store the medicine at room temperature, away from heat, moisture, and direct light.
Ask your pharmacist, doctor, or health caregiver about the best way to dispose of any outdated medicine or medicine no longer needed.
Keep all medicine out of the reach of children and never share your medicine with anyone.

Drugs and Foods to Avoid:
Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.
Make sure your doctor knows if you are also using a blood thinner (Coumadin®).

Warnings While Using This Medicine:
Although it is unlikely that a postmenopausal woman might become pregnant, you should know that using this medicine while you are pregnant could harm the unborn baby. If you think you have become pregnant while using the medicine, tell your doctor right away.
Make sure your doctor knows if you have gallbladder disease, diabetes, heart disease, high blood pressure, high levels of calcium in your blood (hypercalcemia), liver disease, asthma, epilepsy, migraine headaches, kidney disease, high cholesterol, or blood clots.
Taking large doses of estrogens over a long period of time may increase your risk of some kinds of cancer. If you have questions about this risk, talk with your doctor.
Your doctor will need to check your progress at regular visits while you are using this medicine (usually every 6 to 12 months). Be sure to keep all appointments.
Make sure any doctor or dentist who treats you knows that you are using this medicine. This medicine may affect the results of certain medical tests.

Possible Side Effects While Using This Medicine:
Call your doctor right away if you notice any of these side effects:
Blistering, peeling, red skin rash
Lumps in breast (women and men)
Numbness or weakness in your arm or leg, pain in your chest or leg (calf)
Severe headache or vomiting, dizziness, slurred speech
Shortness of breath, coughing up blood
Swelling in your hands, ankles, or feet
Vaginal bleeding of unknown cause

If you notice these less serious side effects, talk with your doctor:
Changes in hair growth
Changes in your vision
Nausea, vomiting, stomach cramps, bloated feeling
Swollen and tender breasts (women and men)
Vaginal itching or discharge

If you notice other side effects that you think are caused by this medicine, tell your doctor.
D) Estradiol (Into the vagina)
Estradiol

Treats hot flashes, painful sexual intercourse, and other symptoms of menopause or low estrogen.

When This Medicine Should Not Be Used:
This medicine is not right for everyone. Do not use it if you had an allergic reaction to estradiol, or if

you are pregnant, or have unusual vaginal bleeding that has not been checked by your doctor. Do not use it if you have liver disease, breast or uterine cancer, problems with blood clots, or had a heart attack or stroke.

How to Use This Medicine:

Cream, Insert, Suppository

Your doctor will tell you how much medicine to use. Do not use more than directed.
Read and follow the patient instructions that come with this medicine. Talk to your doctor or pharmacist if you have any questions.
Vaginal cream:

Measure the cream using the marks on the plastic applicator. Make sure you use the correct mark for your specific dose.

Vaginal ring:

Once the ring is in place, you should not be able to feel it. If you feel uncomfortable, the ring may not be inserted far enough. Gently push the ring farther into your vagina. If you feel pain, talk to your doctor.
The ring may move down accidently. This can happen if you strain to have a bowel movement. Gently push the ring back into place. If the ring comes all the way out, rinse it with warm water and put it back in. Call your doctor if the ring comes out several times.
Remove the ring after 90 days and insert a new one as needed.
Do not flush a used vaginal ring down the toilet. Wrap it with tissue or toilet pair and throw it in the trash.

Vaginal insert:

The insert should be used only in your vagina. Do not swallow the insert.
It is best to use this medicine at the same time each day.
Imvexxy™: Push an insert through the foil of the blister package and hold it with the larger end between your fingers. You may choose to put the insert into your vagina using the lying down or standing up position. Put the insert about 2 inches into your vagina, with the smaller end up, using your finger.
Vagifem®: Do not take the insert out of the applicator. If the insert comes out of the applicator when you open it, carefully put it back in. If the insert falls out of the applicator when you try to insert it, throw it away and use a new applicator and insert.

Store the unopened packages of this medicine at room temperature, away from heat, moisture, and direct light.

Drugs and Foods to Avoid:

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

Some medicines can affect how estradiol works. Tell your doctor if you are using carbamazepine, clarithromycin, erythromycin, itraconazole, ketoconazole, phenobarbital, rifampin, ritonavir, St John's wort, or thyroid medicines.
Do not eat grapefruit or drink grapefruit juice while you are using this medicine.
Ask your doctor before you use other products or medicines in your vagina. You may need to remove the ring first.

Warnings While Using This Medicine:

Pregnancy after menopause is not likely, but if you think you could be pregnant, tell your doctor. This medicine could harm an unborn baby.
Tell your doctor if you are breastfeeding, or if you have kidney disease, asthma, diabetes, edema, endometriosis, epilepsy, migraine headaches, porphyria, lupus, thyroid problems, heart disease, high blood pressure, high cholesterol, hereditary angioedema, bone problems, or a history of cancer. Tell your doctor if you had liver problems caused by pregnancy or estrogen. Tell your doctor if you have any problems with your vagina or in your pelvic area, including prolapse. Tell your doctor if you are having a surgery that requires inactivity for a long time.
This medicine may cause the following problems:

Increased risk of heart attack, stroke, or blood clots
Increased risk of endometrial, breast, ovarian, or uterine cancer
Possible risk of dementia (especially in women 65 years of age or older)
Gallbladder disease
Eye or vision problems
High blood pressure
High cholesterol or fats in the blood

Tell any doctor or dentist who treats you that you are using this medicine. This medicine may affect certain medical test results.
Your doctor will check your progress and the effects of this medicine at regular visits. Keep all appointments.
Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible Side Effects While Using This Medicine:
Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing
Breast lumps or tenderness
Chest pain that may spread, coughing up blood, trouble breathing
Fever, diarrhea, muscle pain, dizziness, fainting
Numbness or weakness on one side of your body, sudden or severe headache, problems with speech or walking
Redness, pain, burning, or itching in or near your vagina
Sudden and severe stomach pain, nausea, vomiting
Swelling in your hands, ankles, or feet
Unusual vaginal bleeding, spotting, discharge, or itching
Vision changes

If you notice these less serious side effects, talk with your doctor:

If you notice other side effects that you think are caused by this medicine, tell your doctor.

E) Estradiol Patch (Absorbed through the skin)
Estradiol

Treats symptoms of menopause (including hot flashes and vaginal problems) in women with a uterus. Also treats low estrogen levels and prevent osteoporosis after menopause.

When This Medicine Should Not Be Used:
This medicine is not right for everyone. Do not use if you had an allergic reaction to estradiol, or if you have unusual vaginal bleeding that has not been checked by your doctor. Do not use it if you have liver disease, breast cancer, estrogen-dependent tumors, bleeding problems, blood clots, dementia, heart or blood vessel disease, or had a heart attack or stroke.

How to Use This Medicine:
Patch

Your doctor will tell you how many patches to use, where to apply them, and how often to apply them. Do not use more patches or apply them more often than your doctor tells you to.
Read and follow the patient instructions that come with this medicine. Talk to your doctor or pharmacist if you have any questions.
Wash your hands with soap and water before and after applying a patch.
Leave the patch in its sealed wrapper until you are ready to put it on. Tear the wrapper open carefully. NEVER CUT the wrapper or the patch with scissors. Do not use any patch that has been cut by accident.
The patient instructions will show the body areas where you can wear the patch. When putting on each new patch, choose a different place within these areas. Do not put the new patch on the same place you wore the last one. Be sure to remove the old patch before applying a new one.
Place the patch on a clean, dry area of your lower stomach or upper buttock area, where there is no oil, lotion, or powder. Do not apply the patch on or near your breasts, over cut or broken skin, or in a spot where it might rub off (including the waistline).
Press the patch firmly in place with your hand for about 10 seconds.
Change your patch on the same days of each week, to help you remember.
If you have any adhesive left on your skin after you remove the patch, allow it to dry for 15 minutes. Then gently rub the sticky area with oil or lotion to remove the adhesive.
You may take a bath, shower, or swim while wearing a patch.
Fold the used patch in half with the sticky side together. Place it in a sturdy childproof container and throw away, out of the reach of children and pets. Do not flush the patch down the toilet.
Missed dose: If you forget to wear or change a patch, put one on as soon as you can. If it is almost time to put on your next patch, wait until then to apply a new patch and skip the one you missed. Do not apply extra patches to make up for a missed dose.
If a patch falls off, just put it back on a different area. If the patch does not stick completely, put on a new patch, but continue to follow your original schedule for changing to a new one.
Store the patches at room temperature in a closed container, away from heat, moisture, and direct light. Do not open the pouch until you are ready to use the patch.

Drugs and Foods to Avoid:
Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

Some foods and medicines can affect how estradiol works. Tell your doctor if you are using carbamazepine, clarithromycin, erythromycin, itraconazole, ketoconazole, phenobarbital, rifampin, ritonavir, St John's wort, thyroid medicine, or a blood thinner (including warfarin).
Do not eat grapefruit or drink grapefruit juice while you are using this medicine.

Warnings While Using This Medicine:

Pregnancy after menopause is not likely, but if you think you could be pregnant, tell your doctor.
This medicine could harm an unborn baby.
Tell your doctor if you are breastfeeding, or if you have kidney disease, asthma, diabetes, endometriosis, seizures, migraine headaches, porphyria, lupus, thyroid problems, hereditary angioedema, edema (swelling), high blood pressure, high cholesterol or triglycerides, obesity, or a history of cancer. Tell your doctor if you have had your uterus (womb) removed (hysterectomy) or if you are having surgery that will require inactivity for a long time.
This medicine may cause the following problems:

Increased risk of heart attack, stroke, or blood clots
Increased risk of endometrial cancer, breast cancer, or uterine cancer
Possible risk of dementia, especially in women 65 years of age and older
Gallbladder disease
Eye or vision problems
High blood pressure
High cholesterol or fats in the blood
Thyroid problems

Tell any doctor or dentist who treats you that you are using this medicine. This medicine may affect certain medical test results.
Your doctor will do lab tests at regular visits to check on the effects of this medicine. Keep all appointments.
Keep all medicine out of the reach of children. Never share your medicine with anyone.

Possible Side Effects While Using This Medicine:
Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing
Blurred or other changes in vision
Breast lumps or tenderness
Chest pain that may spread,, trouble breathing, or coughing up blood
Dark urine or pale stools, nausea, vomiting, loss of appetite, stomach pain, yellow skin or eyes
Fever, diarrhea, muscle pain, dizziness, fainting
Numbness or weakness on one side of your body, sudden or severe headache, problems with vision, speech, or walking
Rapid weight gain, swelling in your hands, ankles, or feet
Redness, pain, burning, or itching in or near your vagina
Unusual vaginal bleeding or heavy bleeding

If you notice these less serious side effects, talk with your doctor:

Headache
Runny or stuffy nose
Skin redness or itching where the patch is placed

If you notice other side effects that you think are caused by this medicine, tell your doctor.

TOXICOLOGY

Clinical Effects

No results available

Range of Toxicity

No results available

Treatment

No results available

ABOUT

How Supplied

No results available

Drug Properties

A) Information on specific products and dosage forms can be obtained by referring to the Tradename List (Product Index)

B) Synonyms

Estradiol
Estradiol, Micronized
Estradiol Acetate
Estradiol Benzoate
Estradiol Cyp
Estradiol Cypionate
Estradiol Enanthate
Estradiolum
Estradiol Valerate

C) Orphan Drug Status

1) This drug has one or more orphan drug designations, which may include approval or withdrawal of status: Access citation for FDA Orphan Drug Information [54].

D) Physicochemical Properties

1) Estradiol

a) Molecular Weight

1) 272.39 [757]

b) Solubility

1) Soluble in dioxane; slightly soluble in chloroform and ether; sparingly soluble in alcohol and acetone; and practically insoluble in water [758]

2) Estradiol Acetate

a) Molecular Weight

1) 314.42 [759]

3) Estradiol Valerate

a) Molecular Weight

1) 356.50 [57]

Storage & Stability

A) Estradiol

1) Preparation

a) General Information

1) NIOSH Group 2 Non-antineoplastics [52]

2) NIOSH: Use of single gloves by anyone handling intact tablets or capsules or administering from a unit-dose package is recommended [52].

3) NIOSH: In the preparation of tablets or capsules, including cutting, crushing, or manipulating, or the handling of uncoated tablets, use double gloves and a protective gown. Prepare in a ventilated control device, if possible. Use respiratory protection if not prepared in a control device. During administration, wear single gloves, and wear eye/face protection if the formulation is hard to swallow or if the patient may resist, vomit, or spit up [52].

4) NIOSH: In the compounding and administration of a hazardous topical drug, use double gloves and a protective gown. Prepare in a biological safety cabinet or a compounding aseptic containment isolator, and use eye/face and respiratory protection if not prepared in a control device. During administration, if there is a potential that the substance could splash or if the patient may resist, use eye/face protection, and if there is inhalation potential use respiratory protection [52].

b) Transdermal route

1) Emulsion

a) Apply and rub emulsion into thighs and calves for 3 minutes on each side until thoroughly absorbed. Rub excess on both hands and buttocks and allow to dry completely before covering with clothing. Wash hands after application [35].

2) Gel

a) Divigel(R)

1) Apply entire contents of the single-dose packet to clean, dry skin of left or right upper thigh. The gel should not be applied to face, breasts, in or around vagina, or to irritated skin. Avoid contact with eyes. Allow to dry before dressing and do not wash application site within 1 hour after application. Wash hands with soap and water after application [38].

b) Estrogel(R)

1) Prime the metered dose pump by fully depressing the spout 2 times for the 93 g pump or 3 times for the 50 and 25 g pumps prior to the first use. Collect gel into palm of hand and apply directly onto dry, clean, unbroken skin of the upper arm and shoulder area. The gel should not be applied directly to breast. Apply gel gently from wrist to shoulder and allow to dry for up to 5 minutes before dressing. It is not necessary to massage or rub in the ge. Wash hands with soap and water after application [13].

c) Elestrin(R)

1) To prime the pump, push the head down slowly and allow it to spring back automatically; repeat until gel comes out. Throw away the first amount of gel (not a full dose) into the trash. Once the pump head has come all the way back up, the pump is ready to use [34].

2) If taking a bath or shower or using a sauna, apply dose afterwards. Dry skin completely before application. Apply dose at the same time each day [34].

3) Hold the pump with the tip facing clean, dry, unbroken skin of the application area of the arm, and press the pump firmly and fully for each pump needed. Gently spread the gel over the entire area of the upper arm and shoulder using 2 fingers. Do not apply to the breast or in or around the vagina. Wash hands after application [34].

4) Allow the gel to dry for at least 5 minutes before dressing, and keep the area dry for as long as possible. Avoid fire, flame, or smoking until the gel has dried. Do not allow others to come in contact with the application area for at least 2 hours. If swimming, wait at least 2 hours before going into the water. Do not apply sunscreen to the area where the gel was applied for at least 25 minutes, and do not apply for 7 or more consecutive days [34].

5) If a dose is missed, do not double the dose. If the next dose is less than 12 hours away, wait and apply the dose the next day. If it is more than 12 hours until the next dose, apply the missed dose and resume normal dosing the next day [34].

3) Transdermal System

a) Place system on clean, dry skin, preferably on the lower abdomen, upper quadrant of the buttock, or outer aspect of the hip. Do not apply to the breasts or waistline. Rotate sites of application with 1 week allowed between applications to a particular site [29][19][8][12].

b) Press Climara (R) system firmly in place for at least 10 seconds, making sure there is good contact, especially around the edges [10]

c) If Climara(R) or Minivelle(R) system falls off reapply to different site; if reapplication not possible, apply new patch to another location for remainder of dosing interval [29][19]

d) Swimming, bathing, or using a sauna may decrease the adhesion of the Climara (R) system and the delivery of estradiol [10]

e) Remove Climara(R) system carefully and slowly, fold it in half, and throw it away. If any adhesive remains on the skin, allow the area to dry for 15 minutes, then gently rub with an oil-based cream or lotion to remove residue [10].

4) Spray

a) Prior to initial application, prime pump by spraying 3 sprays with the cover on. With container being held vertically upright, apply to adjacent, nonoverlapping areas on the inner surface of the forearm, starting near the elbow. Allow to dry for 2 minutes before covering with clothing, and do not wash the site for 1 hour after application. Women should cover the application site with clothing if another person may come into contact with that area of the skin after the spray dries [53].

c) Vaginal route

1) Cream

a) The prescribed dose should be measured using the supplied applicator. Gently insert applicator with measured dose deeply into vagina and press plunger downward to original position. Clean the applicator with mild soap and warm water after use [14].

2) Ring

a) The vaginal ring should be inserted as deeply as possible into the upper one-third of the vaginal vault; the exact position is not critical. To remove the ring, hook a finger through the ring and pull. If the ring is removed or falls out any time during the 90-day treatment period, rinse the ring in lukewarm water and reinsert [15].

3) Insert

a) Using the supplied applicator for Vagifem(R), gently insert into the vagina as far as it can comfortably go without force, or until half of the applicator is inside the vagina, whichever is less [16].

b) Insert Imvexxy(TM) intravaginally with the smaller end up for a depth of about 2 inches into the vaginal canal [5].

B) Estradiol Acetate

1) Preparation

a) General Information

1) NIOSH Group 2 Non-antineoplastics [52]

2) NIOSH: Use of single gloves by anyone handling intact tablets or capsules or administering from a unit-dose package is recommended [52].

3) NIOSH: In the preparation of tablets or capsules, including cutting, crushing, or manipulating, or the handling of uncoated tablets, use double gloves and a protective gown. Prepare in a ventilated control device, if possible. Use respiratory protection if not prepared in a control device. During administration, wear single gloves, and wear eye/face protection if the formulation is hard to swallow or if the patient may resist, vomit, or spit up [52].

b) Vaginal route

1) Administration

a) Wash hands thoroughly before and after inserting vaginal ring [59]

b) Press the opposite sides of the vaginal ring and insert into the vagina [59]

c) The patient may reposition estradiol acetate vaginal ring with finger if needed. If the ring is totally expelled from the vagina, it should be rinsed with lukewarm water and reinserted [59].

d) To remove, wash hands and hook finger through ring and gently pull downward [59].

C) Estradiol Cypionate

1) Preparation

a) General Information

1) NIOSH Group 2 Non-antineoplastics [52]

2) NIOSH: In the preparation and administration of injections, use double gloves and a protective gown. Prepare in a biological safety cabinet or a compounding aseptic containment isolator; eye/face and respiratory protection may be needed. Prepare compounds in a closed system drug transfer device. During administration, if there is a potential that the substance could splash or if the patient may resist, use eye/face protection. Administer certain dosage forms via a closed system drug transfer device [52].

b) Intramuscular route

1) Preparation

a) If crystals form because estradiol cypionate vials had been stored at lower temperatures than what is recommended, they may be redissolved by warming and shaking the vial [55].

D) Estradiol Valerate

1) Preparation

a) General Information

1) NIOSH Group 2 Non-antineoplastics [52]

2) NIOSH: In the preparation and administration of injections, use double gloves and a protective gown. Prepare in a biological safety cabinet or a compounding aseptic containment isolator; eye/face and respiratory protection may be needed. Prepare compounds in a closed system drug transfer device. During administration, if there is a potential that the substance could splash or if the patient may resist, use eye/face protection. Administer certain dosage forms via a closed system drug transfer device [52].

b) Intramuscular route

1) Administration

a) Estradiol valerate injection may be administered with a small gauge needle due to its low viscosity. A dry needle and syringe should be used since use of a wet needle or syringe may cause the solution to become cloudy [57].

b) Inject deep into the upper, outer quadrant of the gluteal muscle [57]

c) If crystals form because estradiol valerate vials had been stored at lower temperatures than what is recommended, they may be redissolved by warming [57].

d) Since the 40-milligram vial provides a high concentration in a low volume, particular care should be taken to administer the full prescribed dose [57].

E) Estradiol

1) Oral route

a) Tablet

1) Store at a controlled room temperature, 20 to 25 degrees C (68 to 77 degrees F); protect from light and close lid tightly [62].

2) Topical application route, Transdermal route

a) Gel/Jelly

1) Store at a controlled room temperature, between 20 and 25 degrees C (68 and 77 degrees F); excursions permitted between 15 and 30 degrees C (59 and 86 degrees F) [74][520][65].

3) Transdermal route

a) Patch, Extended Release

1) Store between 20 and 25 degrees C (66 and 77 degrees F). Store in the protective pouch and apply immediately after removal [29][67][66][521][19]. Excursions permitted between 15 and 30

degrees C (59 and 86 degrees F) [29][521][19].

b) Spray

1) Store at room temperature, between 20 and 25 degrees C (68 and 77 degrees F); do not freeze. Excursions permitted between 15 and 30 degrees C (59 and 86 degrees F) [69].

4) Vaginal route

a) Cream

1) Store at room temperature; protect from temperatures above 40 degrees C (104 degrees F) [73].

b) Insert, Extended Release

1) Store at a controlled room temperature between 15 and 25 degrees C (59 and 77 degrees F) [5][142], with excursions permitted between 15 and 30 degrees C (59 and 86 degrees F) [5].

c) Insert, Extended Release

1) Store at a controlled room temperature, 25 degrees C (77 degrees F); do not refrigerate. Excursions permitted between 15 and 30 degrees C (59 and 86 degrees F) [16].

F) Estradiol Acetate

1) Oral route

a) Tablet

1) Store estradiol acetate tablets at 25 degrees Celsius (77 degrees Fahrenheit); excursions permitted to 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit) [170].

2) Vaginal route

a) Insert, Extended Release

1) Store estradiol acetate vaginal ring at 25 degrees Celsius (77 degrees Fahrenheit); excursions permitted to 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit) [60].

G) Estradiol Cypionate

1) Intramuscular route

a) Oil

1) Store estradiol cypionate injection at controlled room temperature (20 to 25 degrees Celsius or 68 to 77 degrees Fahrenheit) [55].

H) Estradiol Valerate

1) Intramuscular route

a) Oil

1) Store estradiol valerate injection at room temperature [57].

Trade Names

No results available

Regulatory Status

No results available

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627. Product Information: APTIVUS(R) oral capsules, oral solution, tipranavir oral capsules, oral solution. Boehringer Ingelheim Pharmaceuticals, Inc. (per FDA), Ridgefield, CT, 2015.

628. Product Information: TOPAMAX(R) SPRINKLE CAPSULES oral capsules, topiramate oral capsules. Janssen Pharmaceuticals, Inc. (per FDA), Titusville, NJ, 2014.

629. Product Information: HALCION(R) oral tablets, triazolam oral tablets. Pharmacia & Upjohn Co. (per FDA), New York, NY, 2014.

630. Product Information: UBRELVY(TM) oral tablets, ubrogepant oral tablets. Allergan USA Inc (per FDA), Madison, NJ, 2019.

631. Product Information: LEVITRA(R) oral tablets, vardenafil HCl oral tablets. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2014.

632. Product Information: VENCLEXTA(TM) oral tablets, venetoclax oral tablets. AbbVie Inc. (per FDA), North Chicago, IL, 2016.

633. Product Information: Sandimmune(R) oral soft gelatin capsules oral solution intravenous injecton solution, cyclosporine oral soft gelatin capsules oral solution intravenous injecton solution. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2015.

634. Product Information: D.H.E. 45(R) intravenous injection, intramuscular injection, subcutaneous injection, dihydroergotamine mesylate intravenous injection, intramuscular injection, subcutaneous injection. Valeant Pharmaceuticals North America (per DailyMed), Aliso Viejo, CA, 2012.

635. Product Information: TIKOSYN(R) oral capsules, dofetilide oral capsules. Pfizer Labs (per FDA), New York, NY, 2016.

636. Yamreudeewong W, DeBisschop M, Martin LG, et al: Potentially significant drug interactions of class III antiarrhythmic drugs. Drug Safety 2003; 26(6):421-438.

637. Product Information: Ergomar(R) sublingual tablets, ergotamine tartrate sublingual tablets. Rosedale Therapeutics (per manufacturer), Bristol, TN, 2007.

638. Product Information: fentanyl citrate oral lozenge, fentanyl citrate oral lozenge. Par Pharmaceutical (per DailyMed), Spring Valley, NY, 2014.

639. Product Information: ADDYI oral tablets, flibanserin oral tablets. Sprout Pharmaceuticals, Inc. (per FDA), Raleigh, NC, 2015.

640. Product Information: XTAMPZA(TM) ER oral extended-release capsules, oxycodone oral extended-release capsules. Collegium Pharmaceutical Inc (per manufacturer), Canton, MA, 2016.

641. Product Information: OXYCONTIN(R) oral extended-release tablets, oxycodone HCl oral extended-release tablets. Purdue Pharma L.P (per FDA), Stamford, CT, 2015.

642. Product Information: NUPLAZID(TM) oral tablets, pimavanserin oral tablets. ACADIA Pharmaceuticals (per manufacturer), San Diego, CA, 2016.

643. Product Information: ORAP(R) oral tablets, pimozide oral tablets. Teva Select Brands (per DailyMed), Horsham, PA, 2014.

644. Product Information: QUALAQUIN(R) oral capsules, quinine sulfate oral capsules. AR Scientific, Inc., Philadelphia, PA, 2011.

645. Product Information: ASTAGRAF XL(TM) oral extended-release capsules, tacrolimus oral extended-release capsules. Astellas Pharma US, Inc. (per FDA), Northbrook, Il, 2014.

646. Product Information: VERZENIO(TM) oral tablets, abemaciclib oral tablets. Lilly USA LLC (per FDA), Indianapolis, IN, 2017.

647. Product Information: alprazolam oral tablets, alprazolam oral tablets. Sun Pharmaceutical Industries, Inc. (per DailyMed), Cranbury, NJ, 2014.

648. Product Information: CORDARONE(R) oral tablets, amiodarone oral tablets. Wyeth Pharmaceuticals Inc (per FDA), Philadephia, PA, 2018.

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651. Product Information: CADUET(R) oral tablets, amlodipine besylate atorvastatin calcium oral tablets. Pfizer Labs (per FDA), New York, NY, 2015.

652. Product Information: LEXIVA(R) oral tablets, oral suspension, fosamprenavir calcium oral tablets, oral suspension. ViiV Healthcare (per FDA), Research Triangle Park, NC, 2019.

653. Product Information: ABILIFY DISCMELT(R) oral disintegrating tablets, aripiprazole oral disintegrating tablets. Otsuka America Pharmaceutical Inc. (per FDA), Rockville, MD, 2014.

654. Product Information: LIPITOR(R) oral tablets, atorvastatin calcium oral tablets. Parke-Davis (Per FDA), New York, NY, 2014.

655. Product Information: INLYTA(R) oral tablets, axitinib oral tablets. Pfizer Labs (per FDA), New York, NY, 2014.

656. Product Information: BIKTARVY(R) oral tablets, Bictegravir, emtricitabine, tenofovir alafenamide oral tablets. Gilead Sciences, Inc (per FDA), Foster City, CA, 2018.

657. Product Information: VICTRELIS(R) oral capsules, boceprevir oral capsules. Merck Sharp & Dohme Corp. (per FDA), Whitehouse Station, NJ, 2014.

658. Product Information: ALUNBRIG(TM) oral tablets, brigatinib oral tablets. ARIAD Pharmaceuticals, Inc (per FDA), Cambridge, MA, 2017.

659. Nguyen L, Holland J, Miles D, et al: Pharmacokinetic (PK) drug interaction studies of cabozantinib: effect of CYP3A inducer rifampin and inhibitor ketoconazole on cabozantinib plasma PK and effect of cabozantinib on CYP2C8 probe substrate rosiglitazone plasma PK. J Clin Pharmacol 2015; 55(9):1012-1023.
PubMed Abstract: http://www.ncbi.nlm.nih.gov/...

660. Product Information: CABOMETYX(TM) oral tablets, cabozantinib oral tablets. Exelixis, Inc. (per FDA), South San Francisco, CA, 2016.

661. Product Information: TABRECTA(TM) oral tablets, capmatinib oral tablets. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2020.

662. Product Information: PLETAL(R) oral tablets, cilostazol oral tablets. Otsuka America Pharmaceutical, Inc. (per FDA), Rockville, MD, 2015.

663. Product Information: PROPULSID(R) oral tablets, oral suspension, cisapride oral tablets, oral suspension. Janssen Pharmaceutica, Titusville, NJ, 2000.

664. Product Information: BIAXIN(R) XL Filmtab(R) oral extended-release tablets, clarithromycin oral extended-release tablets. AbbVie Inc. (per FDA), North Chicago, IL, 2015.

665. Product Information: codeine sulfate oral tablets, codeine sulfate oral tablets. Lannett Company, Inc. (per DailyMed), Philadelphia, PA, 2014.

666. Product Information: COLCRYS(TM) oral tablets, colchicine oral tablets. Takeda Pharmaceuticals America, Inc. (per FDA), Deerfield, IL, 2014.

667. Product Information: ALIQOPA(TM) intravenous injection, copanlisib intravenous injection. Bayer HealthCare Pharmaceuticals Inc (per FDA), Whippany, NJ, 2017.

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669. Product Information: TAFINLAR oral capsules, dabrafenib oral capsules. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2014.

670. Product Information: DAKLINZA(TM) oral tablets, daclatasvir oral tablets. Bristol-Myers Squibb (per manufacturer), Princeton, NJ, 2015.

671. Product Information: DEXAMETHASONE Intensol(TM) oral concentrate solution, dexamethasone oral concentrate solution. Roxane Laboratories, Inc. (per manufacturer), Columbus, OH, 2007.

672. Product Information: VALIUM(R) oral tablets, diazepam oral tablets. Genentech USA, Inc. (per FDA), South San Francisco, CA, 2013.

673. Product Information: CARDIZEM(R) oral tablets, diltiazem HCl oral tablets. Valeant Pharmaceuticals North America LLC (per FDA), Bridgewater, NJ, 2014.

674. Product Information: DOCEFREZ intravenous injection, docetaxel intravenous injection. Caraco Pharmaceutical Laboratories, Ltd. (per FDA), Detroit, MI, 2014.

675. Product Information: domperidone oral suspension, domperidone oral suspension. Zentiva (per EMC), Guildford, Surrey, United Kingdom, 2014.

676. Product Information: COPIKTRA(TM) oral capsules, duvelisib oral capsules. Verastem Inc (per FDA), Needham, MA, 2018.

677. Product Information: SUSTIVA(R) oral capsules, oral tablets, efavirenz oral capsules, oral tablets. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2017.

678. Product Information: ORILISSA(TM) oral tablets, elagolix oral tablets. AbbVie Inc (per FDA), North Chicago, IL, 2018.

679. Product Information: ZEPATIER(TM) oral tablets, elbasvir, grazoprevir oral tablets. Merck Sharp & Dohme Corp. (per manufacturer), Whitehouse Station, NJ, 2016.

680. Product Information: TRIKAFTA(TM) oral tablets, elexacaftor, tezacaftor, ivacaftor oral tablets; ivacaftor oral tablets. Vertex Pharmaceuticals Incorporated (per manufacturer), Boston, MA, 2019.

681. Product Information: E.E.S.(R) oral suspension, oral film-coated tablets, erythromycin ethylsuccinate oral suspension, oral film-coated tablets. Arbor Pharmaceuticals, Inc. (per FDA), Atlanta, GA, 2012.

682. Product Information: LUNESTA(R) oral tablets, eszopiclone oral tablets. Sunovion Pharmaceuticals Inc. (per FDA), Marlborough, MA, 2014.

683. Product Information: Tavalisse(TM) oral tablets, fostamatinib disodium hexahydrate oral tablets. Rigel Pharmaceuticals Inc (per FDA), South San Francisco, CA, 2018.

684. Product Information: DAURISMO(TM) oral tablets, glasdegib oral tablets. Pfizer Labs (per FDA), New York, NY, 2018.

685. Product Information: INTUNIV(R) oral extended-release tablets, guanfacine oral extended-release tablets. Shire US Inc (per FDA), Lexington, MA, 2016.

686. Product Information: HALDOL(R) Decanoate 100 intramuscular injection, haloperidol decanoate intramuscular injection. Janssen Pharmaceuticals, Inc. (per DailyMed), Titusville, NJ, 2013.

687. Hutchinson MR, Menelaou A, Foster DJ, et al: CYP2D6 and CYP3A4 involvement in the primary oxidative metabolism of hydrocodone by human liver microsomes. Br J Clin Pharmacol 2004; 57(3):287-297.
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688. Product Information: OBREDON oral solution, hydrocodone bitartrate guaifenesin oral solution. Sovereign Pharmaceuticals, LLC (per FDA), Fort Worth, TX, 2014.

689. Product Information: Locoid(R) topical cream, hydrocortisone butyrate 0.1% topical cream. Valeant Pharmaceuticals North America LLC (per FDA), Bridgewater, NJ, 2014.

690. Product Information: LOCOID LIPOCREAM(R) topical cream, hydrocortisone butyrate 0.1% topical cream. Valeant Pharmaceuticals North America LLC (per DailyMed), Bridgewater, NJ, 2014.

691. Product Information: ZYDELIG(R) oral tablets, idelalisib oral tablets. Gilead Sciences Inc (per FDA), Foster City, CA, 2018.

692. Product Information: ifosfamide intravenous injection, ifosfamide intravenous injection. Teva Pharmaceuticals USA, Inc. (per DailyMed), North Wales, PA, 2015.

693. Product Information: GLEEVEC(R) oral tablets, imatinib mesylate oral tablets. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2015.

694. Product Information: CAMPTOSAR(R) intravenous injection, irinotecan intravenous injection. Pharmacia & Upjohn Co (per Manufacturer), New York, NY, 2014.

695. Product Information: ONIVYDE(TM) intravenous injection solution, irinotecan liposome intravenous injection solution. Merrimack Pharmaceuticals, Inc.(per manufacturer), Cambridge, MA, 2015.

696. Product Information: NOURIANZ(TM) oral tablets, istradefylline oral tablets. Kyowa Kirin Inc (per FDA), Bedminster, NJ, 2019.

697. Product Information: SPORANOX(R) oral capsules, itraconazole oral capsules. Janssen Pharmaceuticals, Inc. (per FDA), Titusville, NJ, 2015.

698. Product Information: TYKERB(R) oral tablets, lapatinib oral tablets. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2015.

699. Product Information: VITRAKVI(R) oral capsules, oral solution, larotrectinib oral capsules, oral solution. Loxo Oncology Inc (per FDA), Stamford, CT, 2018.

700. Product Information: DAYVIGO(TM) oral tablets, lemborexant oral tablets. Eisai Inc (per FDA), Woodcliff Lake, NJ, 2019.

701. Product Information: lercanidipine HCl oral film-coated tablets, lercanidipine HCl oral film-coated tablets. Actavis UK Ltd (per EMC), Devon, United Kingdom, 2014.

702. Product Information: CONJUPRI(R) oral tablets, levamlodipine oral tablets. CSPC Ouyi Pharmaceutical Co., Ltd (per FDA), Princeton, NJ, 2019.

703. Product Information: KALETRA(R) oral capsules, lopinavir ritonavir oral capsules. AbbVie Inc. (per FDA), North Chicago, IL, 2015.

704. Product Information: CAPLYTA(R) oral capsules, lumateperone oral capsules. Intra-Cellular Therapies Inc (per FDA), New York, NY, 2019.

705. Product Information: ZEPZELCA(TM) intravenous injection, lurbinectedin intravenous injection. Jazz Pharmaceuticals Inc (per FDA), Palo Alto, CA, 2020.

706. Product Information: SYMPROIC(R) oral tablets, naldemedine oral tablets. Purdue Pharma L.P. (per FDA), Stamford, CT, 2018.

707. Product Information: Starlix(R) oral tablets, nateglinide oral tablets. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2011.

708. Product Information: VIRACEPT(R) oral tablets, oral powder for solution, nelfinavir mesylate oral tablets, oral powder for solution. ViiV Healthcare Company (per FDA), Research Triangle Park, NC, 2015.

709. Product Information: NERLYNX(TM) oral tablets, neratinib oral tablets. Puma Biotechnology, Inc (per FDA), Los Angeles, CA, 2017.

710. Product Information: PROCARDIA XL(R) oral extended release tablets, nifedipine oral extended release tablets. Pfizer Labs (per FDA), New York, NY, 2015.

711. Product Information: SULAR(R) oral film coated extended release tablets, nisoldipine oral film coated extended release tablets. Shionogi Inc. (per DailyMed), Florham Park, NJ, 2013.

712. Product Information: ZOFRAN(R) intravenous injection, ondansetron HCl intravenous injection. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2013.

713. Product Information: ISTURISA(R) oral tablets, osilodrostat oral tablets. Recordati Rare Disease Inc (per FDA), Lebanon, NJ, 2020.

714. Product Information: paclitaxel intravenous injection, paclitaxel intravenous injection. WG Critical Care, LLC (per FDA), Paramus, NJ, 2015.

715. Product Information: IBRANCE(R) oral capsules, palbociclib oral capsules. Pfizer Labs (per manufacturer), New York, NY, 2017.

716. Product Information: TECHNIVIE(TM) oral tablets, ombitasvir paritaprevir ritonavir oral tablets. AbbVie Inc. (per Manufacturer), North Chicago, IL, 2015.

717. Product Information: PEMAZYRE(TM) oral tablets, pemigatinib oral tablets. Incyte Corporation (per FDA), Wilmington, DE, 2020.

718. Product Information: TURALIO(TM) oral capsules, pexidartinib oral capsules. Daiichi Sankyo Inc (per FDA), Basking Ridge, NJ, 2019.

719. Product Information: progesterone intramuscular injection, progesterone intramuscular injection. Watson Pharma, Inc. (per DailyMed), Parsippany, NJ, 2013.

720. Product Information: quinidine gluconate oral extended-release tablets, quinidine gluconate oral extended-release tablets. Richmond Pharmaceuticals, Inc. (per DailyMed), Richmond, VA, 2011.

721. Product Information: RANEXA(R) oral extended-release tablets, ranolazine oral extended-release tablets. Gilead Sciences, Inc. (per FDA), Foster City, CA, 2016.

722. Product Information: PRANDIN(R) oral tablets, repaglinide oral tablets. Novo Nordisk Inc. (per FDA), Plainsboro, NJ, 2017.

723. Product Information: KISQALI(R) oral tablets, ribociclib oral tablets. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2017.

724. Product Information: NURTEC(TM) orally disintegrating tablets, rimegepant orally disintegrating tablets. Biohaven Pharmaceuticals Inc (per FDA), New Haven, CT, 2020.

725. Product Information: QINLOCK(TM) oral tablets, ripretinib oral tablets. Deciphera Pharmaceuticals LLC (per FDA), Waltham, MA, 2020.

726. Product Information: XARELTO(R) oral tablets, rivaroxaban oral tablets. Janssen Pharmaceuticals Inc (per FDA), Titusville, NJ, 2020.

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728. Product Information: SEREVENT(R) DISKUS(R) inhalation powder, salmeterol xinafoate inhalation powder . GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2014.

729. Product Information: ONGLYZA(R) oral tablets, saxagliptin oral tablets. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2017.

730. Patel CG, Li L, Girgis S, et al: Two-way pharmacokinetic interaction studies between saxagliptin and cytochrome P450 substrates or inhibitors: simvastatin, diltiazem extended-release, and ketoconazole. Clin Pharmacol 2011; 3:13-25.
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731. Product Information: RETEVMO(TM) oral capsules, selpercatinib oral capsules. Lilly USA LLC (per FDA), Indianapolis, IN, 2020.

732. Product Information: KOSELUGO(TM) oral capsules, selumetinib oral capsules. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2020.

733. Product Information: OLYSIO(R) oral capsules, simeprevir oral capsules. Janssen Therapeutics (per FDA), Titusville, NJ, 2015.

734. Product Information: ODOMZO(R) oral capsules, sonidegib oral capsules. Novartis Pharmaceuticals (per FDA), East Hanover, NJ, 2015.

735. Product Information: SUTENT(R) oral capsules, sunitinib malate oral capsules. Pfizer Labs (per FDA), New York, NY, 2015.

736. Product Information: tamoxifen citrate oral tablets, tamoxifen citrate oral tablets. Watson Laboratories (per manufacturer), Corona, CA, 2011.

737. Product Information: TEPADINA(R) intravenous, intracavitary, intravesical injection, thiotepa intravenous, intracavitary, intravesical injection . ADIENNE SA (per FDA), Cedar Park, TX, 2017.

738. de Jonge ME, Huitema AD, van Dam SM, et al: Significant induction of cyclophosphamide and thiotepa metabolism by phenytoin. Cancer Chemother Pharmacol 2005; 55(5):507-510.
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739. Product Information: Yondelis intravenous infusion powder concentrate for solution, trabectedin intravenous infusion powder concentrate for solution. Pharma Mar, S.A (per EMA), Madrid, Spain, 2015.

740. Product Information: trazodone HCl oral tablets, trazodone HCl oral tablets. Sun Pharmaceutical Industries , Inc. (per DailyMed), Cranbury, NJ, 2014.

741. Product Information: TUKYSA(TM) oral tablets, tucatinib oral tablets. Seattle Genetics Inc (per FDA), Bothell, WA, 2020.

742. Product Information: Verelan(R) sustained-release oral capsules, verapamil HCl sustained-release oral capsules. Kremers Urban Pharmaceutical Inc. (per FDA), Princeton, NJ, 2014.

743. Product Information: vinblastine sulfate intravenous injection, vinblastine sulfate intravenous injection. Bedford Laboratories (per manufacturer), Bedford, OH, 2012.

744. Product Information: Vincasar PFS(R) intravenous injection solution, vincristine sulfate intravenous injection solution. Teva Pharmaceuticals USA, Inc. (per DailyMed), North Wales, PA, 2014.

745. Product Information: MARQIBO(R) intravenous injection, vincristine sulfate liposome intravenous injection. Acrotech Biopharma LLC (per FDA), East Windsor, NJ, 2020.

746. Product Information: vinorelbine intravenous injection solution, vinorelbine intravenous injection solution. Hospira Inc (per DailyMed), Lake Forest, IL, 2016.

747. Product Information: ZONTIVITY(R) oral tablets, vorapaxar oral tablets. Merck Sharp & Dohme Corp. (per FDA), Whitehouse Station, NJ, 2015.

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749. Product Information: VOSEVI(TM) oral tablets, sofosbuvir velpatasvir voxilaprevir oral tablets. Gilead Sciences Inc (per manufacturer), Foster City, CA, 2017.

750. Product Information: Sonata(R) oral capsules, zaleplon oral capsules. King Pharmaceuticals, Inc. (per FDA), Bristol, TN, 2013.

751. Product Information: GEODON(R) intramuscular injection, ziprasidone mesylate intramuscular injection. Roerig (per FDA), New York, NY, 2014.

752. Product Information: AMBIEN(R) oral tablets, zolpidem tartrate oral tablets. sanofi-aventis U.S. LLC (per FDA), Bridgewater, NJ, 2014.

753. US Pharmacopeial Convention: Hazardous Drugs - Handling in Healthcare Settings. In: 2017 USP Compounding Compendium, US Pharmacopeial Convention, Rockville, MD, 2016.

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757. Product Information: ESTROGEL(R) topical gel, estradiol topical gel. ASCEND Therapeutics,Inc, Herndon, VA, 2008.

758. Reynolds JEF (Ed): Martindale: The Extra Pharmacopeia (CD-ROM Version), Micromedex, Inc, Englewood, CO, 1988.

759. Product Information: Femring(R) vaginal ring, estradiol acetate vaginal ring. Warner Chilcott (US), LLC, Rockaway, NJ, 2010.

760. Institute for Safe Medication Practices: ISMP's list of confused drug names. Institute for Safe Medication Practices. Huntingdon Valley, PA. 2005. Available from URL: http://ismp.org/Tools/confuseddrugnames.pdf.

Last Modified: November 21, 2022

TAB 175-28

Agency Responses to Plaintiffs' Questions: March 1, 2023

Plaintiffs' Question: *Please provide a complete list of the diagnostic codes (ICD-10 codes) programmed in FMMIS for the following drugs (listed by generic name): estradiol (all formulations and combinations listed in the PDL); testosterone (all formulations listed in the PDL); testosterone cypionate (all formulations listed in the PDL); testosterone enanthate (all formulations listed in the PDL); triptorelin pamoate (both the kit and the vial); leuprolide acetate (all formulations listed in the PDL); Metformin HCL (all formulations listed in the PDL).*

Agency Response: The diagnosis codes for drugs subject to an automatic prior authorization or bypass are located at https://ahca.myflorida.com/medicaid/Prescribed_Drug/drug_criteria_pdf/Automated_PA.pdf. This list includes those established for triptorelin pamoate and leuprolide acetate. For prescription drugs that are not on that list and do not require a prior authorization, the Agency does not verify the diagnosis code prior to paying the claim.

Plaintiffs' Question: *Please answer whether the prescribed drug criteria listed at https://ahca.myflorida.com/6edicaid/prescribed_drug/drug_criteria.shtml is an exhaustive list of the criteria relied upon by AHCA in reviewing whether a prescribed drug is medically necessary. If the above is not an exhaustive list, please provide documents indicating all other criteria on which AHCA relies in determining whether a prescribed drug is medically necessary for a particular patient, either during the prior authorization process, or after a claim has been paid (as described by Mr. Brackett).*

Agency Response: Yes, this is an exhaustive list.

Plaintiffs' Question: *Please answer whether Florida's Medicaid managed care plans are required to cover all drugs included in the PDL and, if so, whether the plans must follow the prior authorization requirements as indicated in the PDL.*

Agency Response: Yes, health plans participating in the Statewide Medicaid Managed Care program must cover all drugs on the Preferred Drug List and cannot be more restrictive when covering drugs that have a specific criteria.

Plaintiffs' Question: *Please identify the person who made edits to the GAPMS report on cross-sex hormone therapy dated May 20, 2022 as well as all individuals who accessed the document.*

Agency Response: The Agency identified the employee as Shantrice Greene, who worked as a senior pharmacist. She is no longer with the Agency.

Plaintiffs' Question: *Please provide the number of individuals who received Medicaid coverage for puberty suppression medications to treat gender dysphoria from January 1, 2015 to August 21, 2022.*

Agency Response: Please refer to the data file that was completed on March 1, 2023.

Plaintiffs' Question: *Please provide the number of grievances and the number of appeals filed with Florida Medicaid managed care plans regarding services excluded pursuant to Fla. Admin. Code R. 59G-1.050(7).*

Agency Response: The Agency found one complaint regarding the coverage of services under the challenged exclusion.

Plaintiffs' Question: *Please state whether, and if so, how many, Medicaid fair hearings have resulted in a reversal of a decision to deny coverage for any of the services listed at 59G-1.050(7), prior to the effective date of the Challenged Exclusion.*

Agency Response: The Agency identified zero fair hearings that were prior to the challenged exclusion.

Plaintiffs' Question: *Please provide the number of Medicaid fair hearings regarding a request for coverage of services listed at 59G-1.050(7) since August 21, 2022 including information about the adverse action being appealed and the final outcome.*

Agency Response: The Agency identified zero fair hearings that occurred after the implementation of the challenged exclusion.

Plaintiffs' Question: *Please identify the Florida Department of Health employee(s) who provided the name "Michelle Cretella" or the name of any other consultant who AHCA relied upon or consulted with in the drafting of the 2022 GAPMS Memo.*

Agency Response: All communication that occurred between the Agency and the Department of Health occurred through verbal conversations. Agency staff that participated in these discussions do not recall the specific Department of Health employee who provided the name.

Plaintiffs' Question: *Please identify all individuals who AHCA considered but decided not to use for assistance with drafting the June 2022 GAPMS report on treatment for gender dysphoria.*

Agency Response: Agency staff engaged in verbal communications with individuals that were referred by Dr. Michelle Cretella and do not recall the names of those individuals that were consulted.

Plaintiffs' Question: *Regarding the emails between AHCA and Magellan dated April 20, 2022 to June 3, 2022 (Def_000145166 to Def 000145169), please answer the following:*

- **Question:** *What does CCM mean?*
- **Agency Response:** Change Control Memo
- **Question:** *What does "gender code = B (Both)" mean?*
- **Agency Response:** That a covered outpatient prescription drug can be prescribed to both males and females.
- **Question:** *What is the "internal Gender Dysphoria criteria?"*
- **Agency Response:** The criteria provided to Magellan to utilize when reviewing prior authorization requests for GnRH antagonists.
- **Question:** *What is meaning of the following paragraph: "This internal document serves for GnRHanalog use to delay puberty in adolescents with Gender Dysphoria, but it does not speak to the use of hormone therapy (i.e.anastrozole, etc.).This document was provided by the Agency due to a fair hearing request received for Lupron for a recipient with this diagnosis. All requests*

required vetting by AHCA before a final determination is made, and MMA will continue to do so as instructed."

- **Agency Response:** This paragraph specifically references the internal prior authorization review criteria for GnRH antagonists and requires Magellan only to review requests for that one drug category and not any that involve hormones such as testosterone or estrogen.

TAB 175-36

AACAP Statement Responding to Efforts to ban Evidence-Based Care for Transgender and Gender Diverse Youth

November 8, 2019

Variations in gender expression represent normal and expectable dimensions of human development. They are not considered to be pathological. Health promotion for all youth encourages open exploration of all identity issues, including sexual orientation, gender identity, and/or gender expression according to recognized practice guidelines (1, 2). Research consistently demonstrates that gender diverse youth who are supported to live and/or explore the gender role that is consistent with their gender identity have better mental health outcomes than those who are not (3, 4, 5).

State-based legislation regarding the treatment of transgender youth that directly oppose the evidence-based care recognized by professional societies across multiple disciplines is a serious concern. Many reputable professional organizations, including the American Psychological Association, the American Psychiatric Association, the American Academy of Pediatrics, and the Endocrine Society, which represent tens of thousands of professionals across the United States, recognize natural variations in gender identity and expression and have published clinical guidance that promotes nondiscriminatory, supportive interventions for gender diverse youth based on the current evidence base. These interventions may include, and are not limited to, social gender transition, hormone blocking agents, hormone treatment, and affirmative psychotherapeutic modalities.

The American Academy of Child and Adolescent Psychiatry (AACAP) supports the use of current evidence-based clinical care with minors. AACAP strongly opposes any efforts – legal, legislative, and otherwise – to block access to these recognized interventions. Blocking access to timely care has been shown to increase youths' risk for suicidal ideation and other negative mental health outcomes. Consistent with AACAP's policy against conversion therapy (2), AACAP recommends that youth and their families formulate an individualized treatment plan with their clinician that addresses the youth's unique mental health needs under the premise that all gender identities and expressions are not inherently pathological.

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4. Ryan C, Russell ST, Huebner D, Diaz R, Sanchez J. (2010) Family acceptance in adolescence and the health of LGBT young adults. J Child Adolesc Psychiatr Nurs., 23(4):205–213.
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TAB 175-37

All Policies

Pl. Trial Ex. 037

Care for the Transgender and Gender Nonbinary Patient

The American Academy of Family Physicians (AAFP) recognizes that diversity in gender identity and expression is a normal part of the human existence and does not represent pathology. The AAFP supports access to gender-affirming care for gender-diverse patients, including children and adolescents. Gender-affirming health care is part of comprehensive primary care for many gender-diverse patients, and may include supportive behavioral health care, gender-affirming hormones, puberty blockade, medical procedures, and surgical interventions.

Family physicians are uniquely suited to provide gender-affirming care because of their whole-person focus, ability to create care plans that meet the needs of diverse individuals, and longitudinal relationship with the patient across the entire lifespan. Family physicians who do not provide this care should take steps to ensure that patients requiring gender-affirming services are appropriately referred.

Transgender and gender nonbinary people often face social and economic marginalization, and experience a variety of barriers to healthcare, including overt discrimination, inadequate health insurance coverage, legislative interference in the physician-patient relationship, and poor physicia knowledge of appropriate treatment. The AAFP supports gender-affirming care as an evidence-informed intervention that can promote health equity for gender-diverse individuals, although wide sociopolitical efforts are necessary to further mitigate these barriers and advance equity. The AAF asserts the full spectrum of gender-affirming care should be legal and should remain a treatment decision between a physician and their patient.

The AAFP supports education on gender diversity and gender-affirming care at all levels of medical education, including medical school, residency and continuing professional development. (October 2020 BOD) (July 2022 BOD)

TAB 175-38

Pl. Trial Ex. 038

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents

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abstract

FREE

As a traditionally underserved population that faces numerous health disparities, youth who identify as transgender and gender diverse (TGD) and their families are increasingly presenting to pediatric providers for education, care, and referrals. The need for more formal training, standardized treatment, and research on safety and medical outcomes often leaves providers feeling ill equipped to support and care for patients that identify as TGD and families. In this policy statement, we review relevant concepts and challenges and provide suggestions for pediatric providers that are focused on promoting the health and positive development of youth that identify as TGD while eliminating discrimination and stigma.

INTRODUCTION

In its dedication to the health of all children, the American Academy of Pediatrics (AAP) strives to improve health care access and eliminate disparities for children and teenagers who identify as lesbian, gay, bisexual, transgender, or questioning (LGBTQ) of their sexual or gender identity.[1,2] Despite some advances in public awareness and legal protections, youth who identify as LGBTQ continue to face disparities that stem from multiple sources, including inequitable laws and policies, societal discrimination, and a lack of access to quality health care, including mental health care. Such challenges are often more intense for youth who do not conform to social expectations and norms regarding gender. Pediatric providers are increasingly encountering such youth and their families, who seek medical advice and interventions, yet they may lack the formal training to care for youth that identify as transgender and gender diverse (TGD) and their families.[3]

This policy statement is focused specifically on children and youth that identify as TGD rather than the larger LGBTQ population, providing brief, relevant background on the basis of current available research

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Dr Rafferty conceptualized the statement, drafted the initial manuscript, reviewed and revised the manuscript, approved the final manuscript as submitted, and agrees to be accountable for all aspects of the work.

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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TABLE 1 Relevant Terms and Definitions Related to Gender Care

Term	Definition
Sex	An assignment that is made at birth, usually male or female, typically on the basis of external genital anatomy but sometimes on the basis of internal gonads, chromosomes, or hormone levels
Gender identity	A person's deep internal sense of being female, male, a combination of both, somewhere in between, or neither, resulting from a multifaceted interaction of biological traits, environmental factors, self-understanding, and cultural expectations
Gender expression	The external way a person expresses their gender, such as with clothing, hair, mannerisms, activities, or social roles
Gender perception	The way others interpret a person's gender expression
Gender diverse	A term that is used to describe people with gender behaviors, appearances, or identities that are incongruent with those culturally assigned to their birth sex; gender-diverse individuals may refer to themselves with many different terms, such as transgender, nonbinary, genderqueer,[7] gender fluid, gender creative, gender independent, or noncisgender. "Gender diverse" is used to acknowledge and include the vast diversity of gender identities that exists. It replaces the former term, "gender nonconforming," which has a negative and exclusionary connotation.
Transgender	A subset of gender-diverse youth whose gender identity does not match their assigned sex and generally remains persistent, consistent, and insistent over time; the term "transgender" also encompasses many other labels individuals may use to refer to themselves.
Cisgender	A term that is used to describe a person who identifies and expresses a gender that is consistent with the culturally defined norms of the sex they were assigned at birth
Agender	A term that is used to describe a person who does not identify as having a particular gender
Affirmed gender	When a person's true gender identity, or concern about their gender identity, is communicated to and validated from others as authentic
MTF; affirmed female; trans female	Terms that are used to describe individuals who were assigned male sex at birth but who have a gender identity and/or expression that is asserted to be more feminine
FTM; affirmed male; trans male	Terms that are used to describe individuals who were assigned female sex at birth but who have a gender identity and/or expression that is asserted to be more masculine
Gender dysphoria	A clinical symptom that is characterized by a sense of alienation to some or all of the physical characteristics or social roles of one's assigned gender; also, gender dysphoria is the psychiatric diagnosis in the *DSM-5*, which has focus on the distress that stems from the incongruence between one's expressed or experienced (affirmed) gender and the gender assigned at birth.
Gender identity disorder	A psychiatric diagnosis defined previously in the *DSM-IV* (changed to "gender dysphoria" in the *DSM-5*); the primary criteria include a strong, persistent cross-sex identification and significant distress and social impairment. This diagnosis is no longer appropriate for use and may lead to stigma, but the term may be found in older research.
Sexual orientation	A person's sexual identity in relation to the gender(s) to which they are attracted; sexual orientation and gender identity develop separately.

This list is not intended to be all inclusive. The pronouns "they" and "their" are used intentionally to be inclusive rather than the binary pronouns "he" and "she" and "his" and "her." Adapted from Bonifacio HJ, Rosenthal SM. Gender variance and dysphoria in children and adolescents. *Pediatr Clin North Am*. 2015;62(4):1001–1016. Adapted from Vance SR Jr, Ehrensaft D, Rosenthal SM. Psychological and medical care of gender nonconforming youth. *Pediatrics*. 2014;134(6):1184–1192. DSM-5, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; FTM, female to male; MTF, male to female.

and expert opinion from clinical and research leaders, which will serve as the basis for recommendations. It is not a comprehensive review of clinical approaches and nuances to pediatric care for children and youth that identify as TGD. Professional understanding of youth that identify as TGD is a rapidly evolving clinical field in which research on appropriate clinical management is limited by insufficient funding.[3,4]

DEFINITIONS

To clarify recommendations and discussions in this policy statement, some definitions are provided. However, brief descriptions of human behavior or identities may not capture nuance in this evolving field. "Sex," or "natal gender," is a label, generally "male" or "female," that is typically assigned at birth on the basis of genetic and anatomic characteristics, such as genital anatomy, chromosomes, and sex hormone levels. Meanwhile, "gender identity" is one's internal sense of who one is, which results from a multifaceted interaction of biological traits, developmental influences, and environmental conditions. It may be male, female, somewhere in between, a combination of both, or neither (ie, not conforming to a binary conceptualization of gender). Self-recognition of gender identity develops over time, much the same way as a child's physical body does. For some people, gender identity can be fluid, shifting in different contexts. "Gender expression" refers to the wide array of ways people display their gender through clothing, hair styles, mannerisms, or social roles. Exploring different ways of expressing gender is common for children and may challenge social expectations. The way others interpret this expression is referred to as "gender perception" (Table 1).[5,6]

These labels may or may not be congruent. The term "cisgender" is used if someone identifies and expresses a gender that is consistent with the culturally defined norms of the sex that was assigned at birth. "Gender diverse" is an umbrella term to describe an ever-evolving array of labels that people may apply when their gender identity, expression, or even perception does not conform

to the norms and stereotypes others expect of their assigned sex. "Transgender" is usually reserved for a subset of such youth whose gender identity does not match their assigned sex and generally remains persistent, consistent, and insistent over time. These terms are not diagnoses; rather, they are personal and often dynamic ways of describing one's own gender experience.

Gender identity is not synonymous with "sexual orientation," which refers to a person's identity in relation to the gender(s) to which they are sexually and romantically attracted. Gender identity and sexual orientation are distinct but interrelated constructs.[8] Therefore, being transgender does not imply a sexual orientation, and people who identify as transgender still identify as straight, gay, bisexual, etc, on the basis of their attractions. (For more information, *The Gender Book*, found at www.thegenderbook.com, is a resource with illustrations that are used to highlight these core terms and concepts.)

EPIDEMIOLOGY

In population-based surveys, questions related to gender identity are rarely asked, which makes it difficult to assess the size and characteristics of the population that is TGD. In the 2014 Behavioral Risk Factor Surveillance System of the Centers for Disease Control and Prevention, only 19 states elected to include optional questions on gender identity. Extrapolation from these data suggests that the US prevalence of adults who identify as transgender or "gender nonconforming" is 0.6% (1.4 million), ranging from 0.3% in North Dakota to 0.8% in Hawaii.[9] On the basis of these data, it has been estimated that 0.7% of youth ages 13 to 17 years (~150 000) identify as transgender.[10] This number is much higher than previous estimates, which were extrapolated from individual states or specialty clinics, and is likely an underestimate given the stigma regarding those who openly identify as transgender and the difficulty in defining "transgender" in a way that is inclusive of all gender-diverse identities.[11]

There have been no large-scale prevalence studies among children and adolescents, and there is no evidence that adult statistics reflect young children or adolescents. In the 2014 Behavioral Risk Factor Surveillance System, those 18 to 24 years of age were more likely than older age groups to identify as transgender (0.7%).[9] Children report being aware of gender incongruence at young ages. Children who later identify as TGD report first having recognized their gender as "different" at an average age of 8.5 years; however, they did not disclose such feelings until an average of 10 years later.[12]

MENTAL HEALTH IMPLICATIONS

Adolescents and adults who identify as transgender have high rates of depression, anxiety, eating disorders, self-harm, and suicide.[13–20] Evidence suggests that an identity of TGD has an increased prevalence among individuals with autism spectrum disorder, but this association is not yet well understood.[21,22] In 1 retrospective cohort study, 56% of youth who identified as transgender reported previous suicidal ideation, and 31% reported a previous suicide attempt, compared with 20% and 11% among matched youth who identified as cisgender, respectively.[13] Some youth who identify as TGD also experience gender dysphoria, which is a specific diagnosis given to those who experience impairment in peer and/or family relationships, school performance, or other aspects of their life as a consequence of the incongruence between their assigned sex and their gender identity.[23]

There is no evidence that risk for mental illness is inherently attributable to one's identity of TGD. Rather, it is believed to be multifactorial, stemming from an internal conflict between one's appearance and identity, limited availability of mental health services, low access to health care providers with expertise in caring for youth who identify as TGD, discrimination, stigma, and social rejection.[24] This was affirmed by the American Psychological Association in 2008[25] (with practice guidelines released in 2015[8]) and the American Psychiatric Association, which made the following statement in 2012:

> *Being transgender or gender variant implies no impairment in judgment, stability, reliability, or general social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identity or expression.... [Such] discrimination and lack of equal civil rights is damaging to the mental health of transgender and gender variant individuals.*[26]

Youth who identify as TGD often confront stigma and discrimination, which contribute to feelings of rejection and isolation that can adversely affect physical and emotional well-being. For example, many youth believe that they must hide their gender identity and expression to avoid bullying, harassment, or victimization. Youth who identify as TGD experience disproportionately high rates of homelessness, physical violence (at home and in the community), substance abuse, and high-risk sexual behaviors.[5,6,12,27–31] Among the 3 million HIV testing events that were reported in 2015, the highest percentages of new infections were among women who identified as transgender[32] and were also at particular risk for not knowing their HIV status.[30]

GENDER-AFFIRMATIVE CARE

In a gender-affirmative care model (GACM), pediatric providers offer developmentally appropriate care that is oriented toward understanding and appreciating the youth's gender experience. A strong, nonjudgmental partnership with youth and their families can facilitate exploration of complicated emotions and gender-diverse expressions while allowing questions and concerns to be raised in a supportive environment.[5] In a GACM, the following messages are conveyed:

- transgender identities and diverse gender expressions do not constitute a mental disorder;
- variations in gender identity and expression are normal aspects of human diversity, and binary definitions of gender do not always reflect emerging gender identities;
- gender identity evolves as an interplay of biology, development, socialization, and culture; and
- if a mental health issue exists, it most often stems from stigma and negative experiences rather than being intrinsic to the child.[27,33]

The GACM is best facilitated through the integration of medical, mental health, and social services, including specific resources and supports for parents and families.[24] Providers work together to destigmatize gender variance, promote the child's self-worth, facilitate access to care, educate families, and advocate for safer community spaces where children are free to develop and explore their gender.[5] A specialized gender-affirmative therapist, when available, may be an asset in helping children and their families build skills for dealing with gender-based stigma, address symptoms of anxiety or depression, and reinforce the child's overall resiliency.[34,35] There is a limited but growing body of evidence that suggests that using an integrated affirmative model results in young people having fewer mental health concerns whether they ultimately identify as transgender.[24,36,37]

In contrast, "conversion" or "reparative" treatment models are used to prevent children and adolescents from identifying as transgender or to dissuade them from exhibiting gender-diverse expressions. The Substance Abuse and Mental Health Services Administration has concluded that any therapeutic intervention with the goal of changing a youth's gender expression or identity is inappropriate.[33] Reparative approaches have been proven to be not only unsuccessful[38] but also deleterious and are considered outside the mainstream of traditional medical practice.[29,39–42] The AAP described reparative approaches as "unfair and deceptive."[43] At the time of this writing,* conversion therapy was banned by executive regulation in New York and by legislative statutes in 9 other states as well as the District of Columbia.[44]

Pediatric providers have an essential role in assessing gender concerns and providing evidence-based information to assist youth and families in medical decision-making. Not doing so can prolong or exacerbate gender dysphoria and contribute to abuse and stigmatization.[35] If a pediatric provider does not feel prepared to address gender concerns when they occur, then referral to a pediatric or mental health provider with more expertise is appropriate. There is little research on communication and efficacy with transfers in care for youth who identify as TGD, particularly from pediatric to adult providers.

DEVELOPMENTAL CONSIDERATIONS

Acknowledging that the capacity for emerging abstract thinking in childhood is important to conceptualize and reflect on identity, gender-affirmation guidelines are being focused on individually tailored interventions on the basis of the physical and cognitive development of youth who identify as TGD.[45] Accordingly, research substantiates that children who are prepubertal and assert an identity of TGD know their gender as clearly and as consistently as their developmentally equivalent peers who identify as cisgender and benefit from the same level of social acceptance.[46] This developmental approach to gender affirmation is in contrast to the outdated approach in which a child's gender-diverse assertions are held as "possibly true" until an arbitrary age (often after pubertal onset) when they can be considered valid, an approach that authors of the literature have termed "watchful waiting." This outdated approach does not serve the child because critical support is withheld. Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized; in watchful waiting, it is also assumed that notions of gender identity become fixed at a certain age. The approach is also influenced by a group of early studies with validity concerns, methodologic flaws, and limited follow-up on children who identified as TGD and, by adolescence, did not seek further treatment ("desisters").[45,47] More robust and current research suggests that, rather than focusing on who a child will become, valuing them for who they are, even at a young age, fosters secure attachment and resilience, not only for the child but also for the whole family.[5,45,48,49]

* For more information regarding state-specific laws, please contact the AAP Division of State Government Affairs at stgov@aap.org.

MEDICAL MANAGEMENT

Pediatric primary care providers are in a unique position to routinely inquire about gender development in children and adolescents as part of recommended well-child visits[50] and to be a reliable source of validation, support, and reassurance. They are often the first provider to be aware that a child may not identify as cisgender or that there may be distress related to a gender-diverse identity. The best way to approach gender with patients is to inquire directly and nonjudgmentally about their experience and feelings before applying any labels.[27,51]

Many medical interventions can be offered to youth who identify as TGD and their families. The decision of whether and when to initiate gender-affirmative treatment is personal and involves careful consideration of risks, benefits, and other factors unique to each patient and family. Many protocols suggest that clinical assessment of youth who identify as TGD is ideally conducted on an ongoing basis in the setting of a collaborative, multidisciplinary approach, which, in addition to the patient and family, may include the pediatric provider, a mental health provider (preferably with expertise in caring for youth who identify as TGD), social and legal supports, and a pediatric endocrinologist or adolescent-medicine gender specialist, if available.[6,28] There is no prescribed path, sequence, or end point. Providers can make every effort to be aware of the influence of their own biases. The medical options also vary depending on pubertal and developmental progression.

Clinical Setting

In the past year, 1 in 4 adults who identified as transgender avoided a necessary doctor's visit because of fear of being mistreated.[31] All clinical office staff have a role in affirming a patient's gender identity. Making flyers available or displaying posters related to LGBTQ health issues, including information for children who identify as TGD and families, reveals inclusivity and awareness. Generally, patients who identify as TGD feel most comfortable when they have access to a gender-neutral restroom. Diversity training that encompasses sensitivity when caring for youth who identify as TGD and their families can be helpful in educating clinical and administrative staff. A patient-asserted name and pronouns are used by staff and are ideally reflected in the electronic medical record without creating duplicate charts.[52,53] The US Centers for Medicare and Medicaid Services and the National Coordinator for Health Information Technology require all electronic health record systems certified under the Meaningful Use incentive program to have the capacity to confidentially collect information on gender identity.[54,55] Explaining and maintaining confidentiality procedures promotes openness and trust, particularly with youth who identify as LGBTQ.[1] Maintaining a safe clinical space can provide at least 1 consistent, protective refuge for patients and families, allowing authentic gender expression and exploration that builds resiliency.

Pubertal Suppression

Gonadotrophin-releasing hormones have been used to delay puberty since the 1980s for central precocious puberty.[56] These reversible treatments can also be used in adolescents who experience gender dysphoria to prevent development of secondary sex characteristics and provide time up until 16 years of age for the individual and the family to explore gender identity, access psychosocial supports, develop coping skills, and further define appropriate treatment goals. If pubertal suppression treatment is suspended, then endogenous puberty will resume.[20,57,58]

Often, pubertal suppression creates an opportunity to reduce distress that may occur with the development of secondary sexual characteristics and allow for gender-affirming care, including mental health support for the adolescent and the family. It reduces the need for later surgery because physical changes that are otherwise irreversible (protrusion of the Adam's apple, male pattern baldness, voice change, breast growth, etc) are prevented. The available data reveal that pubertal suppression in children who identify as TGD generally leads to improved psychological functioning in adolescence and young adulthood.[20,57–59]

Pubertal suppression is not without risks. Delaying puberty beyond one's peers can also be stressful and can lead to lower self-esteem and increased risk taking.[60] Some experts believe that genital underdevelopment may limit some potential reconstructive options.[61] Research on long-term risks, particularly in terms of bone metabolism[62] and fertility,[63] is currently limited and provides varied results.[57,64,65] Families often look to pediatric providers for help in considering whether pubertal suppression is indicated in the context of their child's overall well-being as gender diverse.

Gender Affirmation

As youth who identify as TGD reflect on and evaluate their gender identity, various interventions may be considered to better align their gender expression with their underlying identity. This process of reflection, acceptance, and, for some, intervention is known as "gender affirmation." It was formerly referred to as "transitioning," but many view the process as an affirmation and acceptance of who they have always been rather than a transition

TABLE 2 The Process of Gender Affirmation May Include ≥1 of the Following Components

Component	Definition	General Age Range[a]	Reversibility[a]
Social affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities	Any	Reversible
Puberty blockers	Gonadotropin-releasing hormone analogues, such as leuprolide and histrelin	During puberty (Tanner stage 2–5)[b]	Reversible[c]
Cross-sex hormone therapy	Testosterone (for those who were assigned female at birth and are masculinizing); estrogen plus androgen inhibitor (for those who were assigned male at birth and are feminizing)	Early adolescence onward	Partially reversible (skin texture, muscle mass, and fat deposition); irreversible once developed (testosterone: Adam's apple protrusion, voice changes, and male pattern baldness; estrogen: breast development); unknown reversibility (effect on fertility)
Gender-affirming surgeries	"Top" surgery (to create a male-typical chest shape or enhance breasts); "bottom" surgery (surgery on genitals or reproductive organs); facial feminization and other procedures	Typically adults (adolescents on case-by-case basis[d])	Not reversible
Legal affirmation	Changing gender and name recorded on birth certificate, school records, and other documents	Any	Reversible

[a] Note that the provided age range and reversibility is based on the little data that are currently available.

[b] There is limited benefit to starting gonadotropin-releasing hormone after Tanner stage 5 for pubertal suppression. However, when cross-sex hormones are initiated with a gradually increasing schedule, the initial levels are often not high enough to suppress endogenous sex hormone secretion. Therefore, gonadotropin-releasing hormone may be continued in accordance with the Endocrine Society Guidelines.[68]

[c] The effect of sustained puberty suppression on fertility is unknown. Pubertal suppression can be, and often is indicated to be, followed by cross-sex hormone treatment. However, when cross-sex hormones are initiated without endogenous hormones, then fertility may be decreased.[68]

[d] Eligibility criteria for gender-affirmative surgical interventions among adolescents are not clearly defined between established protocols and practice. When applicable, eligibility is usually determined on a case-by-case basis with the adolescent and the family along with input from medical, mental health, and surgical providers.[68–71]

from 1 gender identity to another. Accordingly, some people who have gone through the process prefer to call themselves "affirmed females, males, etc" (or just "females, males, etc"), rather than using the prefix "trans-." Gender affirmation is also used to acknowledge that some individuals who identify as TGD may feel affirmed in their gender without pursuing medical or surgical interventions.[7,66]

Supportive involvement of parents and family is associated with better mental and physical health outcomes.[67] Gender affirmation among adolescents with gender dysphoria often reduces the emphasis on gender in their lives, allowing them to attend to other developmental tasks, such as academic success, relationship building, and future-oriented planning.[64] Most protocols for gender-affirming interventions incorporate World Professional Association of Transgender Health[35] and Endocrine Society[68] recommendations and include ≥1 of the following elements (Table 2):

1. Social Affirmation: This is a reversible intervention in which children and adolescents express partially or completely in their asserted gender identity by adapting hairstyle, clothing, pronouns, name, etc. Children who identify as transgender and socially affirm and are supported in their asserted gender show no increase in depression and only minimal (clinically insignificant) increases in anxiety compared with age-matched averages.[48] Social affirmation can be complicated given the wide range of social interactions children have (eg, extended families, peers, school, community, etc). There is little guidance on the best approach (eg, all at once, gradual, creating new social networks, or affirming within existing networks, etc). Pediatric providers can best support families by anticipating and discussing such complexity proactively, either in their own practice or through enlisting a qualified mental health provider.

2. Legal Affirmation: Elements of a social affirmation, such as a name and gender marker, become official on legal documents, such as birth certificates, passports, identification cards, school documents, etc. The processes for making these changes depend on state laws and may require specific documentation from pediatric providers.

3. Medical Affirmation: This is the process of using cross-sex hormones to allow adolescents who have initiated puberty to develop secondary sex characteristics of the opposite biological sex. Some changes are partially reversible if hormones are stopped, but others become

irreversible once they are fully developed (Table 2).

4. Surgical Affirmation: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults,[35,68] they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.[69–71]

For some youth who identify as TGD whose natal gender is female, menstruation, breakthrough bleeding, and dysmenorrhea can lead to significant distress before or during gender affirmation. The American College of Obstetrics and Gynecology suggests that, although limited data are available to outline management, menstruation can be managed without exogenous estrogens by using a progesterone-only pill, a medroxyprogesterone acetate shot, or a progesterone-containing intrauterine or implantable device.[72] If estrogen can be tolerated, oral contraceptives that contain both progesterone and estrogen are more effective at suppressing menses.[73] The Endocrine Society guidelines also suggest that gonadotrophin-releasing hormones can be used for menstrual suppression before the anticipated initiation of testosterone or in combination with testosterone for breakthrough bleeding (enables phenotypic masculinization at a lower dose than if testosterone is used alone).[68] Masculinizing hormones in natal female patients may lead to a cessation of menses, but unplanned pregnancies have been reported, which emphasizes the need for ongoing contraceptive counseling with youth who identify as TGD.[72]

HEALTH DISPARITIES

In addition to societal challenges, youth who identify as TGD face several barriers within the health care system, especially regarding access to care. In 2015, a focus group of youth who identified as transgender in Seattle, Washington, revealed 4 problematic areas related to health care:

1. safety issues, including the lack of safe clinical environments and fear of discrimination by providers;
2. poor access to physical health services, including testing for sexually transmitted infections;
3. inadequate resources to address mental health concerns; and
4. lack of continuity with providers.[74]

This study reveals the obstacles many youth who identify as TGD face in accessing essential services, including the limited supply of appropriately trained medical and psychological providers, fertility options, and insurance coverage denials for gender-related treatments.[74]

Insurance denials for services related to the care of patients who identify as TGD are a significant barrier. Although the Office for Civil Rights of the US Department of Health and Human Services explicitly stated in 2012 that the nondiscrimination provision in the Patient Protection and Affordable Care Act includes people who identify as gender diverse,[75,76] insurance claims for gender affirmation, particularly among youth who identify as TGD, are frequently denied.[54,77] In 1 study, it was found that approximately 25% of individuals who identified as transgender were denied insurance coverage because of being transgender.[31] The burden of covering medical expenses that are not covered by insurance can be financially devastating, and even when expenses are covered, families describe high levels of stress in navigating and submitting claims appropriately.[78] In 2012, a large gender center in Boston, Massachusetts, reported that most young patients who identified as transgender and were deemed appropriate candidates for recommended gender care were unable to obtain it because of such denials, which were based on the premise that gender dysphoria was a mental disorder, not a physical one, and that treatment was not medically or surgically necessary.[24] This practice not only contributes to stigma, prolonged gender dysphoria, and poor mental health outcomes,[77] but it may also lead patients to seek nonmedically supervised treatments that are potentially dangerous.[24] Furthermore, insurance denials can reinforce a socioeconomic divide between those who can finance the high costs of uncovered care and those who cannot.[24,77]

The transgender youth group in Seattle likely reflected the larger TGD population when they described how obstacles adversely affect self-esteem and contribute to the perception that they are undervalued by society and the health care system.[74,77] Professional medical associations, including the AAP, are increasingly calling for equity in health care provisions regardless of gender identity or expression.[1,8,23,72] There is a critical need for investments in research on the prevalence, disparities, biological underpinnings, and standards of care relating to gender-diverse populations. Pediatric providers who work with state government and insurance officials can play an essential role in advocating for

stronger nondiscrimination policies and improved coverage.

There is a lack of quality research on the experience of youth of color who identify as transgender. One theory suggests that the intersection of racism, transphobia, and sexism may result in the extreme marginalization that is experienced among many women of color who identify as transgender,[79] including rejection from their family and dropping out of school at younger ages (often in the setting of rigid religious beliefs regarding gender),[80] increased levels of violence and body objectification,[81] 3 times the risk of poverty compared with the general population,[31] and the highest prevalence of HIV compared with other risk groups (estimated as high as 56.3% in 1 meta-analysis).[30] One model suggests that pervasive stigma and oppression can be associated with psychological distress (anxiety, depression, and suicide) and adoption of risk behaviors by such youth to obtain a sense of validation toward their complex identities.[79]

FAMILY ACCEPTANCE

Research increasingly suggests that familial acceptance or rejection ultimately has little influence on the gender identity of youth; however, it may profoundly affect young people's ability to openly discuss or disclose concerns about their identity. Suppressing such concerns can affect mental health.[82] Families often find it hard to understand and accept their child's gender-diverse traits because of personal beliefs, social pressure, and stigma.[49,83] Legitimate fears may exist for their child's welfare, safety, and acceptance that pediatric providers need to appreciate and address. Families can be encouraged to communicate their concerns and questions. Unacknowledged concerns can contribute to shame and hesitation in regard to offering support and understanding,[84] which is essential for the child's self-esteem, social involvement, and overall health as TGD.[48,85–87] Some caution has been expressed that unquestioning acceptance per se may not best serve questioning youth or their families. Instead, psychological evidence suggests that the most benefit comes when family members and youth are supported and encouraged to engage in reflective perspective taking and validate their own and the other's thoughts and feelings despite divergent views.[49,82]

In this regard, suicide attempt rates among 433 adolescents in Ontario who identified as "trans" were 4% among those with strongly supportive parents and as high as 60% among those whose parents were not supportive.[85] Adolescents who identify as transgender and endorse at least 1 supportive person in their life report significantly less distress than those who only experience rejection. In communities with high levels of support, it was found that nonsupportive families tended to increase their support over time, leading to dramatic improvement in mental health outcomes among their children who identified as transgender.[88]

Pediatric providers can create a safe environment for parents and families to better understand and listen to the needs of their children while receiving reassurance and education.[83] It is often appropriate to assist the child in understanding the parents' concerns as well. Despite expectations by some youth with transgender identity for immediate acceptance after "coming out," family members often proceed through a process of becoming more comfortable and understanding of the youth's gender identity, thoughts, and feelings. One model suggests that the process resembles grieving, wherein the family separates from their expectations for their child to embrace a new reality. This process may proceed through stages of shock, denial, anger, feelings of betrayal, fear, self-discovery, and pride.[89] The amount of time spent in any of these stages and the overall pace varies widely. Many family members also struggle as they are pushed to reflect on their own gender experience and assumptions throughout this process. In some situations, youth who identify as TGD may be at risk for internalizing the difficult emotions that family members may be experiencing. In these cases, individual and group therapy for the family members may be helpful.[49,78]

Family dynamics can be complex, involving disagreement among legal guardians or between guardians and their children, which may affect the ability to obtain consent for any medical management or interventions. Even in states where minors may access care without parental consent for mental health services, contraception, and sexually transmitted infections, parental or guardian consent is required for hormonal and surgical care of patients who identify as TGD.[72,90] Some families may take issue with providers who address gender concerns or offer gender-affirming care. In rare cases, a family may deny access to care that raises concerns about the youth's welfare and safety; in those cases, additional legal or ethical support may be useful to consider. In such rare situations, pediatric providers may want to familiarize themselves with relevant local consent laws and maintain their primary responsibility for the welfare of the child.

SAFE SCHOOLS AND COMMUNITIES

Youth who identify as TGD are becoming more visible because gender-diverse expression is increasingly admissible in the media, on social media, and in schools and communities. Regardless of whether a youth with a gender-diverse

identity ultimately identifies as transgender, challenges exist in nearly every social context, from lack of understanding to outright rejection, isolation, discrimination, and victimization. In the US Transgender Survey of nearly 28 000 respondents, it was found that among those who were out as or perceived to be TGD between kindergarten and eighth grade, 54% were verbally harassed, 24% were physically assaulted, and 13% were sexually assaulted; 17% left school because of maltreatment.[31] Education and advocacy from the medical community on the importance of safe schools for youth who identify as TGD can have a significant effect.

At the time of this writing,* only 18 states and the District of Columbia had laws that prohibited discrimination based on gender expression when it comes to employment, housing, public accommodations, and insurance benefits. Over 200 US cities have such legislation. In addition to basic protections, many youth who identify as TGD also have to navigate legal obstacles when it comes to legally changing their name and/or gender marker.[54] In addition to advocating and working with policy makers to promote equal protections for youth who identify as TGD, pediatric providers can play an important role by developing a familiarity with local laws and organizations that provide social work and legal assistance to youth who identify as TGD and their families.

School environments play a significant role in the social and emotional development of children. Every child has a right to feel safe and respected at school, but for youth who identify as TGD, this can be challenging. Nearly every aspect of school life may present safety concerns and require negotiations regarding their gender expression, including name/pronoun use, use of bathrooms and locker rooms, sports teams, dances and activities, overnight activities, and even peer groups. Conflicts in any of these areas can quickly escalate beyond the school's control to larger debates among the community and even on a national stage.

The formerly known Gay, Lesbian, and Straight Education Network (GLSEN), an advocacy organization for youth who identify as LGBTQ, conducts an annual national survey to measure LGBTQ well-being in US schools. In 2015, students who identified as LGBTQ reported high rates of being discouraged from participation in extracurricular activities. One in 5 students who identified as LGBTQ reported being hindered from forming or participating in a club to support lesbian, gay, bisexual, or transgender students (eg, a gay straight alliance, now often referred to as a genders and sexualities alliance) despite such clubs at schools being associated with decreased reports of negative remarks about sexual orientation or gender expression, increased feelings of safety and connectedness at school, and lower levels of victimization. In addition, >20% of students who identified as LGBTQ reported being blocked from writing about LGBTQ issues in school yearbooks or school newspapers or being prevented or discouraged by coaches and school staff from participating in sports because of their sexual orientation or gender expression.[91]

One strategy to prevent conflict is to proactively support policies and protections that promote inclusion and safety of all students. However, such policies are far from consistent across districts. In 2015, GLSEN found that 43% of children who identified as LGBTQ reported feeling unsafe at school because of their gender expression, but only 6% reported that their school had official policies to support youth who identified as TGD, and only 11% reported that their school's antibullying policies had specific protections for gender expression.[91] Consequently, more than half of the students who identified as transgender in the study were prevented from using the bathroom, names, or pronouns that aligned with their asserted gender at school. A lack of explicit policies that protected youth who identified as TGD was associated with increased reported victimization, with more than half of students who identified as LGBTQ reporting verbal harassment because of their gender expression. Educators and school administrators play an essential role in advocating for and enforcing such policies. GLSEN found that when students recognized actions to reduce gender-based harassment, both students who identified as transgender and cisgender reported a greater connection to staff and feelings of safety.[91] In another study, schools were open to education regarding gender diversity and were willing to implement policies when they were supported by external agencies, such as medical professionals.[92]

Academic content plays an important role in building a safe school environment as well. The 2015 GLSEN survey revealed that when positive representations of people who identified as LGBTQ were included in the curriculum, students who identified as LGBTQ reported less hostile school environments, less victimization and greater feelings of safety, fewer school absences because of feeling unsafe, greater feelings of connectedness to their school

* For more information regarding state-specific laws, please contact the AAP Division of State Government Affairs at stgov@ aap.org.

community, and an increased interest in high school graduation and postsecondary education.[91] At the time of this writing,* 8 states had laws that explicitly forbade teachers from even discussing LGBTQ issues.[54]

MEDICAL EDUCATION

One of the most important ways to promote high-quality health care for youth who identify as TGD and their families is increasing the knowledge base and clinical experience of pediatric providers in providing culturally competent care to such populations, as recommended by the recently released guidelines by the Association of American Medical Colleges.[93] This begins with the medical school curriculum in areas such as human development, sexual health, endocrinology, pediatrics, and psychiatry. In a 2009–2010 survey of US medical schools, it was found that the median number of hours dedicated to LGBTQ health was 5, with one-third of US medical schools reporting no LGBTQ curriculum during the clinical years.[94]

During residency training, there is potential for gender diversity to be emphasized in core rotations, especially in pediatrics, psychiatry, family medicine, and obstetrics and gynecology. Awareness could be promoted through the inclusion of topics relevant to caring for children who identify as TGD in the list of core competencies published by the American Board of Pediatrics, certifying examinations, and relevant study materials. Continuing education and maintenance of certification activities can include topics relevant to TGD populations as well.

* For more information regarding state-specific laws, please contact the AAP Division of State Government Affairs at stgov@ aap.org.

RECOMMENDATIONS

The AAP works toward all children and adolescents, regardless of gender identity or expression, receiving care to promote optimal physical, mental, and social well-being. Any discrimination based on gender identity or expression, real or perceived, is damaging to the socioemotional health of children, families, and society. In particular, the AAP recommends the following:

1. that youth who identify as TGD have access to comprehensive, gender-affirming, and developmentally appropriate health care that is provided in a safe and inclusive clinical space;
2. that family-based therapy and support be available to recognize and respond to the emotional and mental health needs of parents, caregivers, and siblings of youth who identify as TGD;
3. that electronic health records, billing systems, patient-centered notification systems, and clinical research be designed to respect the asserted gender identity of each patient while maintaining confidentiality and avoiding duplicate charts;
4. that insurance plans offer coverage for health care that is specific to the needs of youth who identify as TGD, including coverage for medical, psychological, and, when indicated, surgical gender-affirming interventions;
5. that provider education, including medical school, residency, and continuing education, integrate core competencies on the emotional and physical health needs and best practices for the care of youth who identify as TGD and their families;
6. that pediatricians have a role in advocating for, educating, and developing liaison relationships with school districts and other community organizations to promote acceptance and inclusion of all children without fear of harassment, exclusion, or bullying because of gender expression;
7. that pediatricians have a role in advocating for policies and laws that protect youth who identify as TGD from discrimination and violence;
8. that the health care workforce protects diversity by offering equal employment opportunities and workplace protections, regardless of gender identity or expression; and
9. that the medical field and federal government prioritize research that is dedicated to improving the quality of evidence-based care for youth who identify as TGD.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
GACM: gender-affirmative care model
GLSEN: Gay, Lesbian, and Straight Education Network
LGBTQ: lesbian, gay, bisexual, transgender, or questioning
TGD: transgender and gender diverse

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ACOG COMMITTEE OPINION

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Committee on Gynecologic Practice and Committee on Health Care for Underserved Women

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women in collaboration with committee members Beth Cronin, MD and Colleen K. Stockdale MD, MS.

Health Care for Transgender and Gender Diverse Individuals

ABSTRACT: An estimated 150,000 youth and 1.4 million adults living in the United States identify as transgender. This Committee Opinion offers guidance on providing inclusive and affirming care as well as clinical information on hormone therapy and preventive care; it also cites existing resources for those seeking information on the care of transgender adolescents. The social and economic marginalization of transgender individuals is widespread, which leads to health care inequities and poorer health outcomes for this population. To reduce the inequities experienced by the transgender community, the provision of inclusive health care is essential. Obstetrician–gynecologists should strive to make their offices open to and inclusive for all individuals and should seek out education to address health care disparities, both in their individual practices and in the larger health care system. In order to provide the best care for patients, it is useful to know which health care professionals to include in a referral network for primary care and to have many clinician and surgeon options given the many different therapies available and the different sites at which these therapies are offered. It is important to remember that although hormone therapy is a medically necessary treatment for many transgender individuals with gender dysphoria, not all transgender patients experience gender dysphoria and not everyone desires hormone treatment. Gender-affirming hormone therapy is not effective contraception. Sexually active individuals with retained gonads who do not wish to become pregnant or cause pregnancy in others should be counseled about the possibility of pregnancy if they are having sexual activity that involves sperm and oocytes. Although being knowledgeable about the medications used for gender transition and potential risks and side effects is important, specific certification for prescribing them is not required and should not be a limiting factor in helping patients access care.

Recommendations and Conclusions

The American College of Obstetricians and Gynecologists makes the following conclusions and recommendations regarding health care for transgender and gender diverse individuals:

The American College of Obstetricians and Gynecologists opposes discrimination on the basis of gender identity, urges public and private health insurance plans to cover necessary services for individuals with gender dysphoria, and advocates for inclusive, thoughtful, and affirming care for transgender individuals.

- Obstetrician–gynecologists should make their offices inclusive and inviting to all individuals who need obstetric or gynecologic health care. They should take steps to educate themselves and their medical teams about appropriate language and the health care needs of transgender patients.
- Fertility and parenting desires should be discussed early in the process of transition, before the initiation of hormone therapy or gender affirmation surgery.
- Gender-affirming hormone therapy is not effective contraception. Sexually active individuals with retained gonads who do not wish to become pregnant

or cause pregnancy in others should be counseled about the possibility of pregnancy if they are having sexual activity that involves sperm and oocytes.

- The majority of medications used for gender transition are common and can be safely prescribed by a wide variety of health care professionals with appropriate training and education, including, but not limited to, obstetrician–gynecologists, family or internal medicine physicians, endocrinologists, advanced practice clinicians, and psychiatrists.
- Hysterectomy with or without bilateral salpingo-oophorectomy is medically necessary for patients with gender dysphoria who desire this procedure.
- To guide preventive medical care, any anatomical structure present that warrants screening should be screened, regardless of gender identity.

Background

Transgender and *gender diverse* individuals face harassment, discrimination, and rejection within society. Lack of awareness, knowledge, and sensitivity as well as bias from health care professionals leads to inadequate access to, underuse of, and inequities within the health care system for transgender patients. Throughout this document, the term transgender will be used to refer to anyone who identifies as transgender, gender diverse, and *genderqueer*, while acknowledging that there are vast individual differences and variations in preferred terminology. (See Box 1 for related terminology and definitions.) This Committee Opinion provides guidance for obstetrician–gynecologists on both routine screening and transition care. Obstetrician–gynecologists should be aware of the unique needs of transgender individuals and be prepared to assist them with preventive health care, as well as have knowledge of hormone and surgical therapies. The American College of Obstetricians and Gynecologists opposes discrimination on the basis of *gender identity*, urges public and private health insurance plans to cover necessary services for individuals with gender dysphoria and advocates for inclusive, thoughtful, and affirming care for transgender individuals. Although there is some overlap in clinical and psychosocial care for adolescents and adults, there are some issues specific to adolescents. The American College of Obstetricians and Gynecologists supports the provision of appropriate and evidence-based care for transgender and gender diverse adolescents. For guidance on the medical and surgical care of transgender adolescents, see the World Professional Association for Transgender Health (1), the Endocrine Society (2), and the Pediatric Endocrine Society (3).

It is important for obstetrician–gynecologists and other health care professionals to be familiar with appropriate terminology when caring for patients. *Transgender* is a broad term used for people whose gender identity or *gender expression* differs from their assigned *sex* at birth. For the purposes of clarity, *sex* is

Box 1. Terminology and Definitions

Chestfeeding: Some masculine-identified individuals use this term to describe the act of feeding their child from their chest regardless of whether they have had chest surgery.

Cisgender: A term used to describe a person whose gender identity aligns with those typically associated with the sex assigned to them at birth.

Gender Identity: A person's internal sense of self and how they fit into the world, from the perspective of gender.

Gender Dysphoria: Distress that accompanies the incongruence between one's experienced and expressed gender and one's assigned or natal gender.

Gender Expression: The outward manner in which individuals express or display their gender. This may include choices in clothing and hairstyle or speech and mannerisms. Gender identity and gender expression may differ; for example, a woman (transgender or cisgender) may have an androgynous appearance, or a man (transgender or cisgender) may have a feminine form of self-expression.

Transgender: A person whose gender identity differs from the sex that was assigned at birth. May be abbreviated to trans. A transgender man is someone with a male gender identity and a female birth assigned sex; a transgender woman is someone with a female gender identity and a male birth assigned sex. A nontransgender person may be referred to as cisgender (cis means same side in Latin).

Gender Nonconforming: A person whose gender identity differs from that which was assigned at birth, but may be more complex, fluid, multifaceted, or otherwise less clearly defined than a transgender person.

Genderqueer: Blurring the lines around gender identity and sexual orientation. Genderqueer individuals typically embrace a fluidity of gender identity and sometimes sexual orientation.

Nonbinary: Transgender or gender nonconforming person who identifies as neither male nor female.

Sex: Historically has referred to the sex assigned at birth, based on assessment of external genitalia, as well as chromosomes and gonads. In everyday language is often used interchangeably with gender, however there are differences, which become important in the context of transgender people.

Sexual Orientation: Describes sexual attraction only and is not directly related to gender identity. The sexual orientation of transgender people should be defined by the individual. It is often described based on the lived gender; a transgender woman attracted to other women would be a lesbian, and a transgender man attracted to other men would be a gay man.

Gender Fluidity: Having different gender identities at different times

(Continued)

Agender: "Without gender"; individuals identifying as having no gender identity

Gender Expansiveness: Conveys a wider, more flexible range of gender identity or expression than typically associated with the binary gender system

Transmasculine and Transfeminine: Terms to describe gender nonconforming or nonbinary persons, based on the directionality of their gender identity. A transmasculine person has a masculine spectrum gender identity, with the sex of female listed on their original birth certificate. A transfeminine person has a feminine spectrum gender identity, with the sex of male listed on their original birth certificate. In portions of these Guidelines, in the interest of brevity and clarity, transgender men or women are inclusive of gender nonconforming or nonbinary persons on the respective spectra.

They/Them/Their: Neutral pronouns used by some who have a nonbinary or nonconforming gender identity.

Transsexual: A more clinical term which had historically been used to describe those transgender people who sought medical intervention (hormones, surgery) for gender affirmation. This term is less commonly used in present day; however, some individuals and communities maintain a strong and affirmative connection to this term.

Cross Dresser/Drag Queen/Drag King: These terms generally refer to those who may wear the clothing of a gender that differs from the sex which they were assigned at birth for entertainment, self-expression, or sexual pleasure. Some cross dressers and people who dress in drag may exhibit an overlap with components of a transgender identity. The term *transvestite* is no longer used in the English language and is considered pejorative.

Adapted from Human Rights Campaign. Glossary of terms. Available at: http://www.hrc.org/resources/glossary-of-terms. Retrieved June 1, 2020; MacDonald T. Transgender parents and chest/breastfeeding. St. Petersburg, FL: KellyMom; 2018. Available at: https://kellymom.com/bf/got-milk/transgender-parentschestbreastfeeding/. Retrieved June 18, 2020; UCSF Transgender Care. Terminology and definitions. In: Deutsch MB, editor. Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people. 2nd ed. San Francisco, CA: UCSF Transgender Care; 2016. p. 15-6. Available at: https://transcare.ucsf.edu/guidelines/terminology. Retrieved June 18, 2020; Human Rights Campaign. New Facebook gender options validated by HRC report on gender expansive youth. Washington, DC: HRC; 2014. Available at: https://www.hrc.org/press/newfacebook-gender-options-validated-by-hrc-report-on-gender-expansive-you. Retrieved June 18, 2020; and American Psychiatric Association. What is gender dysphoria? Washington, DC: APA; 2016. Available at: https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria. Retrieved May 28, 2020.

defined as the presence of specific anatomy or chromosomes. Gender is a social construct, made up of attitudes, feelings, and behaviors that a culture associates with either males or females; terminology often varies by geographic region, culture, and individual preference (4) (Box 1). *Gender nonconformity* is the extent to which a person's gender identity, role, or expression differs from the cultural norms described for a specific sex (5). *Sexual orientation* refers to sexual attraction only and is separate from gender identity. It is important to differentiate these concepts and terms when caring for patients (Fig. 1).

An estimated 150,000 youth (aged 13–17 years) and 1.4 million adults (aged 18 years and older) living in the United States identify as transgender (6). Analysis of data collected on adults in 19 states by the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System found that 55% of transgender individuals identified as White, 16% identified as African American or Black, 21% identified as Latino or Hispanic, and 8% identified as another race or ethnicity (7). Although more data on the experiences and needs of the transgender community is now available, there are important gaps in the literature and additional research is needed.

The World Professional Association for Transgender Health (an international, multidisciplinary professional society representing the specialties of medicine, psychology, social sciences, and law) released the following statement in 2010: "the expression of gender characteristics, including identities, that are not stereotypically associated with one's assigned sex at birth is a common and culturally diverse human phenomenon [that] should not be judged as inherently pathological or negative" (8). Although a diagnosis of *gender dysphoria* as defined in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, currently is the only way for many individuals to obtain insurance coverage for necessary services, many experts agree that gender dysphoria is not a psychological condition and does not necessarily belong in the Diagnostic and Statistical Manual of Mental Disorders (Box 2). Gender dysphoria can result in psychologic dysfunction, depression, suicidal ideation, and even death (9). It is important to remember that although some gender nonconforming people will experience gender dysphoria at some point in their lives, not all will; and for many, dysphoria is not persistent if appropriately addressed. The term "gender incongruence" is slated to replace "gender dysphoria" in the International Classification of Diseases, 11th edition.

The social and economic marginalization of transgender individuals is widespread, which leads to health care inequities and poorer health outcomes for this population. The 2015 National Transgender Discrimination Survey, comprised of 27,715 participants from throughout the United States who identified as transgender, trans, genderqueer, nonbinary, and other identities on the transgender identity spectrum, reported that 29% of respondents were currently living in poverty, compared with 14% of the general U.S. population (10). Thirty percent had experienced homelessness during their lifetime and 12% did so during the past year. Notably, homeless transgender individuals may be denied access to shelters or placed in inappropriate housing because of their gender; 26% of homeless

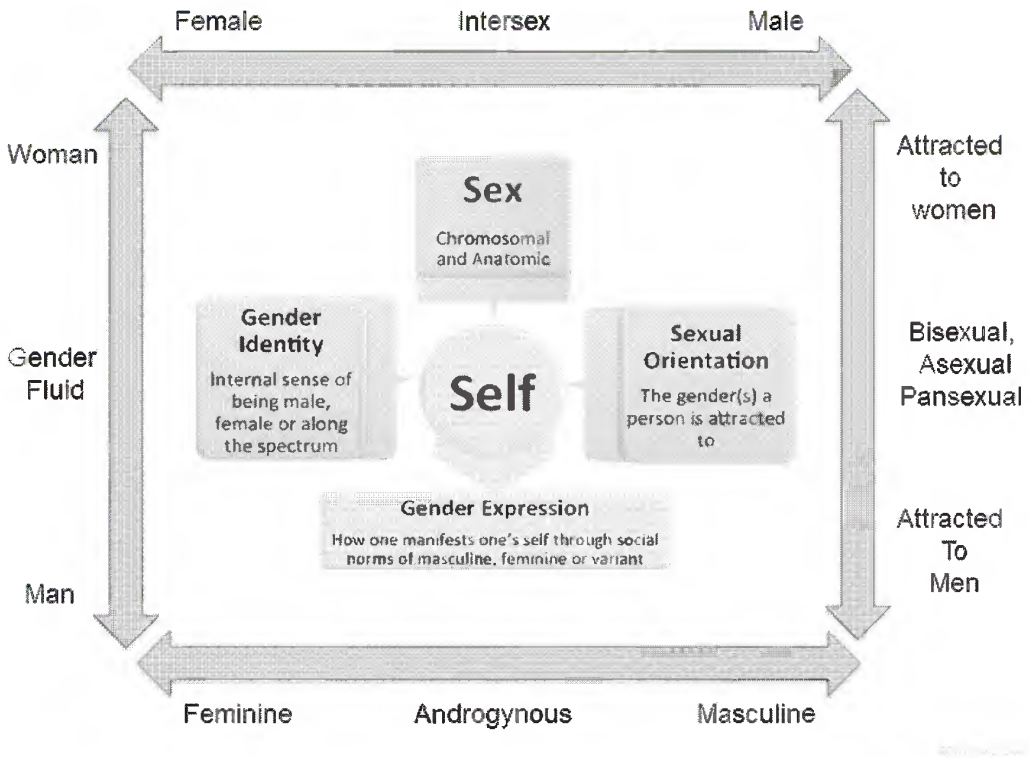

Figure 1. Concepts of Sex and Gender. Reprinted from Concepts of sex and gender. Mayo Clinic. Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved. https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/transgender-facts/art-20266812.

respondents reported avoiding shelters because of fear of being mistreated, and 70% of those using shelters reported some form of mistreatment. Additionally, 20% of respondents reported experience in sex work, drug sales, and other work currently criminalized (10).

To reduce the inequities experienced by the transgender community, the provision of inclusive health care is essential. Obstetrician–gynecologists should strive to make their offices open to and inclusive for all individuals and should seek out education to address health care disparities, both in their individual practices and in the larger health care system.

Barriers to Health Care

Transgender individuals face substantial barriers to accessing health care, including health care professionals' bias and lack of general knowledge about best practices, as well as the failure of many health insurance plans to cover the cost of hormone therapy and supplies, mental health services, or gender affirmation surgery and restrictions on care imposed by prohibitive health care systems. One in four respondents to the Transgender Discrimination Survey had experienced insurance coverage obstacles, such as coverage denials for care related to gender transition or routine care. More than half (55%) had been denied coverage for transition-related surgery, and 25% were denied coverage for hormone therapy (10). These barriers exist despite evidence that such interventions are safe, effective, and medically necessary. The consequences of inadequate care are substantial. Providing accessible, inclusive, gender-affirming care helps to reduce barriers and allow more individuals to obtain the care they need.

Creating a safe and affirming health care environment for all patients, including transgender individuals, is essential. Transgender individuals face discrimination from health care professionals and staff. One-third of respondents reported having at least one negative experience in a health care office related to being transgender, such as being refused care or verbally harassed or having to teach the health care professional about transgender people in order to get appropriate care. In addition, some respondents have experienced physical or sexual abuse in this setting (10). Even higher rates of negative experiences were reported for transgender individuals with disabilities and American Indian, Middle Eastern, and multiracial transgender individuals. For instance, in 2015, 23% of the respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person

Box 2. The American Psychiatric Association's Diagnostic Criteria for Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Reprinted from American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Washington, DC.

(10). Individuals concerned about the way they may be treated by a health care professional are more likely to obtain hormones from friends or unlicensed sources, putting them at risk of inappropriate dosing and the subsequent sequelae. Accessing care from an obstetrician–gynecologist is specifically challenging because these offices have generally been very gendered, women-specific environments, which can be perceived and experienced as exclusive.

Creating an Inclusive Environment

Presenting to a health care office can be stressful and anxiety provoking for a transgender individual. Obstetrician–gynecologists and office staff can create an inclusive environment for transgender patients that will encourage patients to be forthcoming with their concerns and confident that they will be able to obtain the care that they need.

Steps to create a more inclusive environment include the following:

- Increase health care professional knowledge of and comfort with providing care for transgender and gender nonconforming individuals. This includes avoiding making assumptions about patients' sexual orientation, sexual practices, and surgeries and being cognizant of what questions are appropriate (eg, is the question relevant to the care being provided?).
- Train and empower front desk staff, nursing staff, phone staff, billing staff, and others who interact with patients on appropriate ways to ask about names and pronouns (Box 3).
- Review the office space to ensure that images chosen for signage, educational materials, and artwork represent all individuals who may seek health care services.
- Ask all patients what pronouns they use (Box 3).
- Clearly post a sign with the office's nondiscrimination policy.
- Ensure that at least one restroom is gender neutral and accessible to all patients.
- Use patient forms that include check boxes for all gender and sexual orientation options, include blanks for patients to write in their responses, or both. Both the Institute of Medicine (now the National Academies of Sciences, Engineering, and Medicine [11]) and the Joint Commission (12) recommend collection of sexual orientation and gender identity data. Studies demonstrate that patients want to be asked these questions because they feel it is important for their health care professionals to have this information (13).

Box 3. Pronouns

Obstetrician–gynecologists should ask patients about their name and which pronouns they use. Asking all patients routinely for their gender identity and gender pronouns normalizes the interaction and allows patients to disclose without being targeted; good practice includes reciprocal disclosure (eg, "Hello, I am Dr. X and I use she/her pronouns. Is the name on your chart what you would like me to call you? What pronouns do you use?").

The patient's pronouns should be documented in the patient chart.

Common choices include (note: this is not an exhaustive list):

- She/her/hers
- He/him/his
- They/them/their: Neutral pronouns used by some who have a nonbinary or diverse gender identity.

Other gender-neutral pronouns include zie (ze) or hir.

- Create a system where names used by patients (if other than their legal names), gender markers (eg, on medical charts), and pronouns are used for every patient every time.
- Examine the electronic health record system available in offices and hospitals to determine a universal process to ease the communication process for all staff. The Fenway Institute has an excellent resource to guide this process. (14). The patient's name, if different from the individual's legal name, and pronouns used should be noted in the electronic health record.
- Train employees how to apologize for mistakes if they happen.

Gender Transition

Each individual patient will desire different outcomes. Not all patients will want hormone therapy, and not everyone will desire surgery. Some transmasculine patients may desire only masculinizing chest surgery, and other patients will desire hysterectomy and phalloplasty in addition to chest surgery. Medication and surgery are not required parts of transition and should not be required for legally changing one's name or gender marker on official documents (eg, birth certificate, passport, driver's license). Legal transition will vary depending on state laws. Some patients may request letters of support for changing their name or sex on legal documents, and these should be provided. It is important to remember that although hormone therapy is a medically necessary treatment for many transgender individuals with gender dysphoria, not all transgender patients experience gender dysphoria and not everyone desires hormone treatment.

Historically, a referral letter from a mental health professional was required before initiating a patient's gender-affirming hormone therapy. However, current consensus is that an informed consent process without a separate letter from a mental health care professional is more than adequate for initiating therapy for those patients who wish to medically transition. The majority of medications used for gender transition are common and can be safely prescribed by a wide variety of health care professionals with appropriate training and education, including, but not limited to, obstetrician–gynecologists, family or internal medicine physicians, endocrinologists, advanced practice clinicians, and psychiatrists. Although being knowledgeable about the medications used for gender transition and potential risks and side effects is important, specific certification for prescribing them is not required and should not be a limiting factor in helping patients access care. *Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People*, published by the World Professional Association for Transgender Health, is an important resource for health care professionals working with transgender patients (15).

Fertility, Pregnancy, Contraception, and Abortion

Health care professionals' knowledge and awareness about reproductive options need improvement. Pregnancies are possible after transitioning, and perhaps, most important, contraceptive counseling is crucial to prevent undesired pregnancies. Fertility and parenting desires should be discussed early in the process of transition, before the initiation of hormone therapy or gender affirmation surgery. Fertility preservation options for transgender individuals are the same as for those *cisgender* individuals who desire preservation before gonadotoxic cancer therapy or for elective preservation. These options include sperm banking, oocyte preservation, embryo preservation, and in some cases, ovarian or testicular tissue cryopreservation. In addition to the expected pregnancy outcomes with these procedures, patients should be informed of the potential for out-of-pocket costs, which vary by state and insurance coverage.

Transmasculine Individuals

Transmasculine individuals taking testosterone who desire biologically related children may safely achieve pregnancy after the cessation of testosterone. Whether they choose insemination from partner or donor sperm and carry a pregnancy themselves or in vitro fertilization with embryo transfer to a partner or surrogate, transgender masculine individuals have many options for facilitating pregnancy. A 2013 survey of 41 transgender men who experienced pregnancy after transitioning found that two-thirds had used testosterone before pregnancy, with 81% using their own oocytes. Many of the respondents became pregnant within 4 months of stopping testosterone therapy and 32% of these pregnancies were unintended (16). As with cisgender patients, obstetrician–gynecologists should discuss pregnancy intention and prepregnancy health, if appropriate, with transgender patients. The Society of Family Planning provides guidance on contraceptive counseling for transgender and gender diverse people who were assigned female sex at birth (17). Given that contraception can be underutilized in this population because of concerns about adverse effects or access to care, undesired pregnancy is a substantial concern. Abortion access is a critical component to comprehensive reproductive health care for transgender individuals. The 2013 survey also demonstrated that patients experienced low levels of health care professional awareness and knowledge of the needs of transgender individuals (16).

Obstetrician–gynecologists and other health care professionals who care for transmasculine individuals during pregnancy should keep in mind that pregnancy is a gendered experience and pregnancy may trigger feelings of dysphoria or isolation for some patients (18). In addition, some postpartum transgender individuals may not identify as "mothers;" thus, obstetrician–gynecologists and other health care professionals

should be mindful of the language they use. It may be appropriate to use a more neutral term, such as "parent." Some patients may benefit from referral to mental health care professionals with experience in this area. A recent study of patients' experiences recommends providing affirming and inclusive care from prepregnancy through the postpartum period (18). During the postpartum period, patients will need to decide when to restart testosterone. For those making the decision to *chestfeed*, there is little evidence that testosterone passes into breast milk; however, because testosterone may suppress milk production, its use is not recommended until after chestfeeding is complete. Individuals who have had top surgery may still be able to lactate and chestfeed with the help of a support device. Some individuals may have worsening symptoms of dysphoria with lactation, and management of lactation suppression with cabergoline can be discussed with those individuals (19).

Transfeminine Individuals

For those transfeminine individuals preferring to retain their gonads, some may need to use assisted reproductive technologies to achieve pregnancy and others may have return of fertility within months of ceasing hormone therapy. For transfeminine individuals wishing to use their sperm for a pregnancy in a partner or surrogate, some data indicate that long-term estrogen exposure may be associated with testicular damage (20); however, discontinuing hormones for a few months may lead to the return of normal sperm counts. It is best practice to encourage sperm banking before initiation of hormones. Transfeminine individuals who wish to breastfeed may have success with induction of lactation using modifications to the Newman-Goldfarb method (21). A 2018 case report described a transgender woman successfully inducing lactation and continuing breastfeeding at 6 months follow-up (22).

Contraception

Gender-affirming hormone therapy is not effective contraception. Sexually active individuals with retained gonads who do not wish to become pregnant or cause pregnancy in others should be counseled about the possibility of pregnancy if they are having sexual activity that involves sperm and oocytes. Transmasculine individuals should be counseled that lack of menses does not mean they are unable to conceive. All patients should be counseled on barrier use for prevention of sexually transmitted infections. For transmasculine individuals interested in hormonal contraception, testosterone is not a specific contraindication to using any form of contraception. Many transmasculine patients prefer to avoid estrogen-containing methods because they do not want to add estrogen to their system; however, little change is seen in masculinization when these methods are used. Many patients will choose hormonal intrauterine device, contraceptive implant or, depot medroxyprogesterone acetate injection.

Medical Transition

Identifying the patient's goals before initiating masculinizing or feminizing hormone therapy is important. Hormone therapy can be provided in the office, and obstetrician–gynecologists can broaden their skill sets by educating themselves on the provision of transition care. For more details on the provision of hormone therapy for these populations, obstetrician–gynecologists should see resources from the World Professional Association for Transgender Health (8) and the Endocrine Society (20).

Masculinizing Therapy

For many patients, goals of masculinization therapy will include the development of facial hair, deepening of the voice, and increasing body hair and muscle mass. Other effects of masculinizing hormone therapy include the redistribution of subcutaneous fat, change in sweat and odor patterns, and hairline recession, including possible male pattern baldness. Patients also may experience increased libido, cessation of menses, vaginal atrophy, and increased clitoral size. Although testosterone generally causes temporary, and possibly permanent, decreased fertility, discussion about the possibility of continued ovulation is important for those patients with sexual practices that leave them with the potential for pregnancy. Patients should be counseled on current contraception options and their future reproductive life plan. The only absolute contraindications to masculinizing hormone therapy are current pregnancy, unstable coronary artery disease, and polycythemia (hematocrit greater than 55%) (15). Lipid profiles should be monitored in transmasculine patients receiving testosterone therapy (23). High-density lipoprotein levels decrease and triglycerides increase in transmasculine individuals receiving testosterone therapy. Studies have not shown an increased risk of cardiovascular events despite these adverse changes in the lipid profile.

There are many testosterone preparations available in the United States, including injectables, gels, creams, patches, and implantable pellets. Injectable testosterone cypionate is most commonly used subcutaneously, which allows for use of a smaller, less painful needle, but other formulations may be used based on patient preferences or adverse effects. Target ranges for testosterone levels are in the normal physiologic male range (typically 320–1,000 ng/dL) (20). See Table 1 for details on formulations and dosing. In addition to standard health care screening, it is recommended that testosterone levels and hematocrit be monitored every 3 months for the first year and then once or twice a year thereafter.

Patients should be counseled that menses likely will cease within a few months after initiating hormone therapy. If bleeding continues, the obstetrician–gynecologist may consider adding progesterone therapy to facilitate

Table 1. Hormone Preparations and Dosage: Masculinizing Hormone Therapy*

Route	Formulation	Dosage
Oral†	Testosterone undecanoate	160–240 mg/day
Parental (subcutaneous, intramuscular)	Testosterone enanthate, cypionate	50–200 mg/week 100–200 mg/10–14 days
Implant (subcutaneous)	Testosterone pellets, 75 mg	75 mg/pellet
Transdermal	Testosterone gel (1%) Testosterone patch	2.5–10 g/day 2.5–7.5 mg/day

*Dosages should be individualized according to the needs, preferences, and potential contraindications for each patient. Health care professionals also should have knowledge about generics and what medications will be covered by different payers.

†Requires participation in manufacturer monitored program.

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amenorrhea for patients who wish to avoid hysterectomy or endometrial ablation. Testosterone commonly will cause vaginal tissues to atrophy, similar to what is experienced by postmenopausal cisgender women. These tissues may be more susceptible to small amounts of tearing and changes in microbial environment, resulting in increased risk of bacterial vaginosis, cystitis, cervicitis, or dyspareunia (4). In these situations, obstetrician–gynecologists should consider topical treatments such as lubricants, vaginal moisturizers, and topical estrogen. Patients can be counseled that topical estrogen will have minimal systemic absorption and will not interfere with testosterone therapy.

Feminizing Therapy

Feminizing effects of hormone therapy include decreased erectile function, decreased testicular size, breast growth, and increased body fat percentage. Although there are no absolute contraindications to feminizing therapy, risks include venous thromboembolic embolism (VTE), hypertriglyceridemia, development of gallstones, and elevated liver enzymes. Patients on feminizing hormone therapy should be counseled to decrease risk factors for cardiovascular disease, such as smoking. Ethinyl estradiol, which provides better cycle control, may increase the risk of VTE; therefore, because cycle control is unnecessary for transgender women, its use is not indicated. Transdermal preparations of estradiol typically used for hormone replacement therapy are recommended for those with risk factors. If using oral estrogens, 17-β estradiol preparations are preferred (23). In general, prescribing the smallest dose possible to achieve desired effects is recommended. See Table 2 for preparation and dosing suggestions.

Antiandrogens, such as spironolactone, cyproterone acetate, gonadotropin-releasing hormone agonists, and 5-α reductase inhibitors, are used to reduce endogenous testosterone levels, which will decrease masculine characteristics and the amount of estrogen needed (15). Cyproterone is not available in the United States because of concern for hepatotoxicity. Gonadotropin-releasing hormone agonists are often expensive, so are not widely used. Spironolactone, which directly inhibits secretion of testosterone and androgen receptor binding, is the most commonly used antiandrogen in the United States. Because of the risk of hyperkalemia with these medications, it is important to monitor patients' blood pressure and potassium levels (23).

Although currently available data do not provide clear guidance on titration of dosing, it generally should be based on patient goals. Doses should be titrated to physiologic effects, while adjusting estrogen and antiandrogen dosing until in female physiologic range; then, dosing can be modified to focus on further increasing androgen blocking. The goals are to maintain estradiol levels at the mean daily levels for premenopausal women (less than 200 ng/ml) and testosterone in female range (less than 55 ng/dl) (20). Progestins may increase breast development as well as improve libido and mood in some patients. Recommended laboratory surveillance includes estradiol and total testosterone levels, sex hormone binding globulin, and albumin levels every 3 months in the first year to titrate estrogen dosing. After the first year, laboratory tests are necessary only if there are patient or health care professional concerns about adverse effects or after a change in dosage. Patients taking spironolactone also should be tested for potassium and creatinine levels every 3 months for first year and then yearly.

Notably, feminizing hormones do not result in substantial changes to voice. Vocal pitch is secondary to the size and mass of folds of the vocal cords, which are not reversed by the addition of estrogen. Patients with concerns that their voice is incongruent with their gender can be referred to a speech language pathologist who has specific training in this area. If speech therapy does not adequately help, surgical procedures can be considered.

Table 2. Hormone Preparations and Dosage: Feminizing Hormone Therapy*

Route	Formulation	Dosage
Oral	Estradiol	2–4 mg daily
Parental (subcutaneous, intramuscular)	Estradiol valerate	5–30 mg every 2 weeks
Transdermal	Estradiol	0.1–0.4 mg twice weekly
Antiandrogens	Progesterone	20–60 mg by mouth daily
	Medroxyprogesterone acetate	150 mg intramuscularly every 3 months
	GnRH agonist (leuprolide)	3.75–7.5 mg intramuscularly monthly
	Histrelin implant	50 mg implanted every 12 months
	Spironolactone	100–200 mg by mouth daily
	Finasteride	1 mg by mouth daily

*Dosages should be individualized according to the needs, preferences, and potential contraindications for each patient. Health care professionals also should have knowledge about generics and what medications will be covered by different payers.

Abbreviation: GnRH, gonadotropin-releasing hormone.

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Surgical Transition

Some of the surgical procedures described here may not be considered within the scope of practice for an obstetrician–gynecologist, but this section may provide education for clinicians who care for transgender patients before and after surgery. As with any surgical procedure, the quality of care provided before, during, and after surgery greatly affects patient outcomes. Many insurance companies that cover gender affirmation procedures will require a mental health assessment letter before authorization for surgery. Box 4 provides an overview of surgical procedures. For additional information on postoperative care for patients who have had gender-affirming surgery, obstetrician–gynecologists can see resources from the University of San Francisco's Center of Excellence for Transgender Health (4).

Masculinizing Surgery

Transmasculine individuals may choose chest reconstruction, hysterectomy with or without salpingo-oophorectomy, or metoidioplasty, phalloplasty, or both. The U.S. Transgender Survey reported that the majority (97%) of patients had or wanted masculinizing chest surgery; similarly, a majority (79%) of patients had undergone or wanted a hysterectomy. When asked about genital surgeries, only 4% had had metoidioplasty and 53% wanted the procedure in the future; for phalloplasty, 2% had had the procedure and 27% desired it in the future (10). The lower percentage of patients wanting these surgeries is likely multifactorial; limited insurance coverage is one issue. Masculinizing chest surgery, sometimes referred to as "top surgery," generally includes a subcutaneous mastectomy and recontouring to develop a masculine-appearing chest. Factors such as surgeon

Box 4. Surgical Procedures for Transgender Individuals

Masculinizing Surgical Procedures May Include the Following:

- Breast or chest surgery: subcutaneous mastectomy, creation of a male chest
- Genital surgery: hysterectomy with or without salpingo-oophorectomy, reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection or testicular prostheses
- Nongenital, nonbreast surgical interventions: voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures

Feminizing Surgical Procedures May Include the Following:

- Breast or chest surgery: augmentation mammoplasty (implants/lipofilling)
- Genital surgery: penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty
- Nongenital, nonbreast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures

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expertise, body habitus, skin quality, and breast shape and size will influence the surgical approach.

Metoidioplasty to create a neophallus is generally chosen by patients who want genital surgery but are not interested in phalloplasty. Metoidioplasty involves releasing the clitoris, lengthening the urethra to the tip of the phallus, and covering the phallus with neighboring skin. It is possible to have concurrent vaginectomy and scrotoplasty. Patients who choose urethral lengthening will be able to void when standing if they are close to ideal body weight. If a patient desires scrotoplasty, rotational flaps of the labia majora are used to place the scrotum in an anatomic male position. Implants can be placed approximately 6 months later. Phalloplasty generally takes tissue from a donor site, which is shaped into a phallus, allowing for later penile implant to facilitate penetrative intercourse. Most commonly, tissue is taken from the radial forearm, latissimus dorsi, or anterolateral thigh. The decision on the location of the tissue donor site is based on surgeon technique and desired patient outcomes.

Hysterectomy with or without bilateral salpingo-oophorectomy is medically necessary for patients with gender dysphoria who desire this procedure. The route of hysterectomy should be based on clinical findings as well as surgeon and patient preference. Although vaginal hysterectomy will allow for recovery without abdominal scarring, some surgeons may find it to be technically difficult given likely lack of uterine descent and severe vaginal atrophy with a narrow introitus; however, it can be accomplished if desired (24). A genital examination may be challenging and worsen dysphoria for some patients. In these cases, it may be appropriate to conduct the examination under anesthesia before initiating the surgical procedure. Whether the ovaries are removed at the time of hysterectomy will be informed by the patient's fertility desires, long-term plans for hormonal use, and personal preferences and should be considered within a shared decision-making model. Patients should be offered consultation with a fertility specialist before surgical removal of ovaries. Counseling about bone health and cardiovascular protection is challenging because of limited data. Testosterone may have an anabolic effect on cortical bone, and if provided in adequate doses will prevent bone demineralization. No studies have found an increase in the occurrence of cardiovascular events in transmasculine individuals (23), so unless the patient is planning to stop taking testosterone in the future, it is unlikely that the ovaries are necessary to maintain bone or cardiovascular health. More research is needed in this area. Notably while some patients may not plan to stop testosterone, they may do so because of issues such as lack of access. Engaging in shared decision making and counseling regarding the risks and benefits of ovarian preservation before hysterectomy is important.

Feminizing Surgery

Although desire for surgical transition varies depending on the individual, the U.S. Transgender Survey reported that 74% of respondents had either undergone breast augmentation or wanted it in the future. One quarter had undergone orchiectomy and 61% desired it in the future; 87% had undergone vaginoplasty or wanted to do so in the future (10). Potential procedures for transfeminine individuals include breast augmentation, orchiectomy, vaginoplasty, and facial feminization surgeries. It generally is recommended that patients wait at least 6 months after initiating feminizing hormone therapy before undergoing breast augmentation; other experts suggest waiting 2–3 years to maximize hormonal effects (4). Breast augmentation typically is performed with implants, either subglandular or subpectoral depending on a patient's body habitus and desire.

Vaginoplasty involves penile inversion and the creation of a vaginal vault between the rectum and urethra. The vagina is lined with penile skin and labia are created using scrotal skin after orchiectomy is completed. The glans penis is used to create the clitoris. If there is not enough skin available to provide adequate depth, a skin graft is performed. Preoperative electrolysis of the scrotum is recommended to prevent hair from growing in the neovagina.

Successful recovery from this procedure requires patient commitment to a dilation regimen (up to three times per day) to maintain depth and width of the neovagina. Given the limited number of centers providing these procedures, it is not uncommon for a patient to present to their local obstetrician–gynecologist for ongoing postoperative care. The vagina is lined by skin, not mucosa; therefore, it will not lubricate naturally. For patients who are struggling with dilation, they should be counseled to increase the amount of lubricant used and to consider using a smaller-sized dilator to allow for more frequent and deeper dilation; patients can then gradually increase the size of the dilator. Individuals with persistent pain or discomfort with dilation may benefit from a referral to a pelvic floor physical therapist. For individuals presenting with vaginal discharge and odor, sources are most likely sebum, dead skin, or retained semen or lubricant. Those patients should be counseled to clean or douche with soap and water; the addition of vinegar may be considered if strong odor is noted. Patients may present with bleeding or discharge consistent with granulation tissue; this often can be easily treated with silver nitrate.

Cancer Screening

There are insufficient data to determine whether transgender individuals are at increased risk of malignancy compared with the general population. To guide preventive medical care, any anatomical structure present that warrants screening should be screened regardless of gender identity. It may be useful to comprehensively

label laboratory specimens (eg, "male with cervix") to ensure they are appropriately processed.

Transmasculine Individuals

For transmasculine individuals, screening includes breast cancer screening for patients who have breast tissue and cervical cancer screening for those who have a cervix. Before ceasing breast cancer screening, it is important to review operative reports to ensure that mastectomy was performed and not just breast reduction. For those individuals who have undergone mastectomy and reconstruction, there are limited data to support clinical chest examinations in the absence of patient concern (4). The American College of Obstetricians and Gynecologists recommends genetic counseling before surgery for those with a personal or family history of breast cancer or ovarian cancer (25).

Cervical cancer screening should be performed according to age-related guidelines (26–28). Self-collected human papillomavirus (HPV) specimens may be appropriate for those patients who otherwise may not access screening or for whom speculum insertion may be physically difficult or emotionally traumatic; though, to date, there is no patient-collected HPV test approved by the U.S. Food and Drug Administration. Atrophy secondary to testosterone may make cervical cancer screening more challenging. Transmasculine individuals have a 10-fold higher rate of unsatisfactory Pap tests (samples that cannot be evaluated by the laboratory due to a lack of sufficient cells or obscuring factors such as blood) compared with cisgender individuals (29). A 2018 study of transmasculine patients aged 21–64 years reported a high patient preference for self-collected vaginal HPV swabs (greater than 90% preference over swabs collected by health care professionals) and accurate self-collected results consistent with previous studies in cisgender female patients. There was a 71.4% concordance of self-collected samples compared with samples collected by health care professionals (15 of 21 cases detected) (30).

Similar to cisgender women, routine screening for endometrial cancer is not recommended for transmasculine individuals who still have a uterus. Although for transmasculine individuals there is a theoretical concern for increased risk of hyperplasia or malignancy because of the aromatization of exogenous testosterone to estrogen with anovulation leading to unopposed estrogen, there are no data to support this. In fact, most studies demonstrate that the endometrium is atrophic secondary to testosterone use. Therefore, on the basis of limited data, recommendations for screening for endometrial cancer for transmasculine individuals are no different than for cisgender women. Additionally, evaluation of transmasculine individuals with abnormal uterine bleeding are the same as those for cisgender women (31).

Transfeminine Individuals

A neovagina does not require routine cytologic screening. Prostate cancer screening for transfeminine individuals should follow the recommendations for cisgender men (32). Although there are some case reports of prostate cancer in transfeminine individuals, most of these were in individuals who started hormone therapy after 50 years of age; these individuals likely had preexisting lesions before initiating hormone therapy (33). It is likely that transfeminine individuals have a lower risk of breast cancer than cisgender women. A retrospective study of Dutch transfeminine individuals found an estimated breast cancer incidence of 4.1 in 100,000 person-years in comparison with 155 in 100,000 person-years in the cisgender female population (34). This decreased risk is likely because of a substantially decreased length of lifetime exposure to estrogen. However, it is notable that a study of 50 transfeminine individuals found 60% had dense or very dense breasts on mammography, leading to increased rates of false-negative mammogram results (35). General consensus is that screening should begin after 50 years of age and a minimum of 5 years of feminizing hormone use, with a health care professional-patient discussion about the potential harms of over screening (4).

Additional Considerations for Preventive Care

As for all patients, transgender individuals should be counseled about the importance of routine preventive health care. All individuals should be routinely screened for intimate partner violence, depression, substance use, cancer, and other health care needs and should be screened for sexually transmitted infections and counseled about appropriate immunizations based on age and risk factors, including HPV vaccination. As with the general population, screening for intimate partner violence in transgender patients is important and should be performed. A 2017 study found a higher report rate of intimate partner violence in transfeminine individuals (12.1%) when compared with cisgender women (2.7%), transmasculine individuals (6.6%), nonbinary individuals (8.2%), and transgender or gender diverse individuals who did not report a gender identity (9.1%) (36). Screening for mental health issues should be part of standard practice. Forty percent of transgender individuals have attempted suicide at some point during their lifetime (10).

Obstetrician–gynecologists should take a careful and thoughtful medical, family, and surgical history for all patients. Risk assessment for sexually transmitted infections should be based on a patient's behaviors and present anatomy. When performing the physical examination, it is important to remember that patients may have had traumatic examinations in the past. Self-collected vaginal and rectal swabs as well as the option for urine specimens may be appropriate alternatives to physical examination. Obstetrician–gynecologists should follow guidance for transgender individuals in the Centers for Disease Control and Prevention's 2015 STD Treatment Guidelines,

endorsed by the American College of Obstetricians and Gynecologists (37). Screening for human immunodeficiency virus (HIV) in at-risk individuals is of high importance. Among those respondents to the Transgender Discrimination Survey, 1.4% were living with HIV; this is five times higher than the rate of the general U.S. population. The rate in transfeminine individuals was 3.4%, and 19% of Black transfeminine individuals reported living with HIV (10). Obstetrician–gynecologists should counsel patients at high risk of HIV infection on safer sex practices and other prevention methods, as well as the option of preexposure prophylaxis (38).

Conclusion

Accessing health care as a transgender individual often is challenging. Obstetrician–gynecologists may provide comprehensive care for transgender patients at various times in their lives. Obstetrician–gynecologists should make their offices inclusive and inviting to all individuals who need obstetric or gynecologic health care. They should take steps to educate themselves and their medical teams about appropriate language and the health care needs of transgender patients. Putting the patient in the role of educator of the health care professional diminishes the patient-physician relationship. In order to provide the best care for patients, it is useful to know which health care professionals to include in a referral network for primary care and to have many clinician and surgeon options given the many different therapies available and the different sites at which these therapies are offered. Connecting with trans-friendly colleagues is a way to expand access to care for the transgender individuals in the community.

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Attacks on Gender-Affirming and Transgender Health Care

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In 2021, Arkansas became the first state in the country to ban gender-affirming health care for transgender minors. Since then, Tennessee, Arizona, and Alabama have also enacted laws restricting access to gender-affirming care, and 11 other states are considering such bans as of March 2022. Alabama's ban included the harshest penalties of any legislation passed thus far, making the provision of gender-affirming care a felony punishable by up to 10 years in prison. Though legal challenges have so far kept these laws on hold, these health care bans are part of an increasing trend of anti-LGBTQ+ legislation proliferating at the state level, with a record of nearly 240 anti-LGBTQ+ bills already introduced this year.

The Office of Population Affairs at the U.S. Department of Health and Human Services (HHS) defines gender affirming care as "an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. For transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the healthcare system." Gender-affirming care is evidence-based medicine supported by many prestigious medical organizations, and study after study shows that gender-affirming care reduces depression and suicide among transgender youth. ACP and other leading medical organizations have condemned efforts to criminalize gender-affirming care and any care that interferes with the physician-patient relationship.

While restrictions have primarily focused on preventing minors from accessing gender-affirming care, some have also targeted transgender health care for older individuals. In four states, these laws extend bans to adults – applying to those under the age of 19 in Alabama, those under the age of 21 in North Carolina and Oklahoma, and those under 25 in Missouri. Additionally, Arkansas' law has banned insurance coverage of gender-affirming care overall for both public and private insurance plans, as would about half the bills being considered by other states.

The Williams Institute at the UCLA School of Law found that over 58,000 transgender youth and young adults are at risk of losing access to care in states that have restricted access to gender-affirming care or are considering doing so. Beyond immediate impacts, these laws drive stigma and endanger the wellbeing

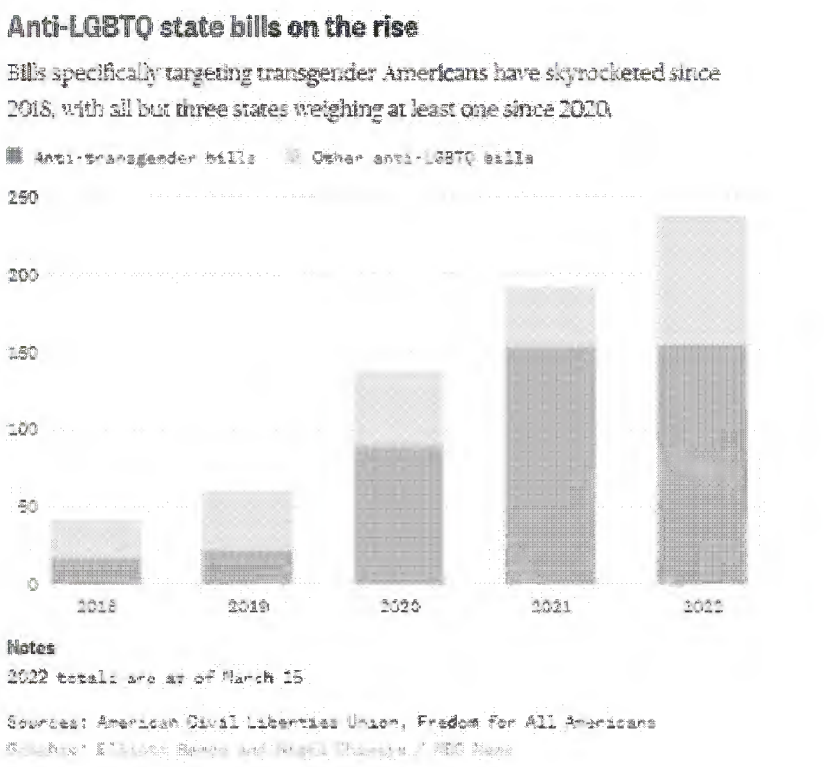
of LGBTQ+ youth. According to the Trevor Project's 2021 National Survey on LGBTQ Youth Mental Health, 94 percent of LGBTQ+ youth reported that recent politics have negatively impacted their mental health.

Most gender-affirming care restrictions either criminalize physicians – sometimes with extreme penalties, such as the bill passed by Idaho's House of Representatives carrying up to a life sentence for those who provide a minor with gender-affirming care – or make them subject to civil penalties or professional discipline through state licensing boards. Bills in multiple states (Alabama, Idaho, Kansas, North Carolina, Oklahoma, South Carolina, and Tennessee) would also establish penalties for parents who facilitate their children's access to gender-affirming care, including by designating this health care as abuse.

While Texas bills to ban gender-affirming care for transgender minors have not passed, the state has used administrative means to restrict access. After Texas Attorney General Ken Paxton issued an opinion describing gender-affirming care as child abuse, Governor Greg Abbott instructed the Texas Department of Family and Protective Services to investigate families with transgender children. This directive, which is currently blocked by a Texas appeals court, would have also imposed criminal penalties on physicians and other licensed professionals who did not report families who provide gender-affirming care to their children.

Florida has also moved to restrict gender-affirming care administratively. The state's Surgeon General released a memo contradicting HHS guidance on gender-affirming care for minors and setting "guidelines" prohibiting gender-affirming care, going as far to say that even social gender transition – such as a change in haircut or name – "should not be a treatment option."

While most of the nearly 240 anti-LGBTQ+ bills introduced so far this year propose restrictions on the lives of transgender children in medical and educational settings, they are part of a growing wave of anti-LGBTQ+ legislation overall. Notable in this trend have been efforts to limit school employees from discussing gender identity, sexual orientation, and race – such as Florida's recently passed "Don't Say Gay" law – and to ban libraries from carrying books related to those topics.



As a result of these initiatives that challenge or deny access to critical health care, criminalize parents, and threaten the removal of children from their homes, some families with the means to do so have fled their states for other jurisdictions. Removing a child from loving parents solely for providing evidence-based and oftentimes life-affirming care is wrong. Alarmingly, these laws have also fueled misinformation that has led to increasing harassment and violence against physicians and other health care workers who provide gender-affirming health care services.

ACP has decried these discriminatory policies against LGBTQ+ people and objected in particular to the interference with the physician-patient relationship and penalization of evidence-based care. ACP believes that physicians and other health care professionals should not fear criminal punishment for providing the medical standard of care, nor should the government attempt to force disclosure of patient information related to gender-affirming care. ACP policy also calls for coverage of comprehensive transgender health care in private and public insurance plans, which about half of these bills would ban. In addition to speaking out against these harmful laws, ACP has joined amicus briefs in legal challenges to the Texas directive and other policies discriminating against transgender people and will continue to support legal and legislative efforts protecting against these medically unsound and dangerous restrictions.

Federal Actions to Address Discrimination against Transgender People

The Biden Administration has taken multiple actions to address this legislative trend. On March 2, 2022, HHS clarified that physicians and other health care personnel are not required to disclose patient information regarding gender-affirming care and that denials of care based on gender identity are illegal.

On March 31, the U.S. Department of Justice wrote to state attorneys general warning that bans on gender-affirming care are unconstitutional and violate multiple federal laws. HHS has also called for physicians and patients who believe they have been discriminated against on the basis of gender identity or disability in seeking to access gender-affirming care to file a complaint with the department's Office of Civil Rights.

HHS also proposed a new rule in December 2021 banning health coverage-related discrimination based on gender identity or sexual orientation. While the new rule has not been finalized, ACP has expressed support.

State Actions to Support Gender-Affirming Care

In response to these bans, at least eight states have introduced legislation this year to prevent discrimination against transgender people in health care or otherwise protect access to gender- affirming care.

- The Hawaii's legislature passed a bill requiring insurers to cover gender-affirming care services if they also cover those treatments for purposes other than gender transition and to provide clear information about coverage of gender-affirming care.
- A Georgia bill would prohibit public insurance plans from discriminating on the basis of gender identity, including through denial of gender-affirming hormone therapy, and would repeal conflicting laws.
- A bill in Vermont would allow minors to consent to non-surgical gender-affirming care.
- A Maryland bill would ensure Medicaid coverage of comprehensive transgender health care.
- Washington state proposed legislation addressing the need to ensure access to gender- affirming care and other forms of health care in mergers, acquisitions, and contracting affiliations.
- California, Minnesota, and New York have responded to efforts in Texas and other states that designate gender-affirming care as abuse by introducing legislation that would block officials in their states from complying with out-of-state laws or judgments penalizing parents for providing gender-affirming care.

Resources

- Prohibiting Gender-Affirming Medical Care for Youth – Williams Institute at UCLA School of Law
- Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians (2015)
- ACP Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship (2012)
- *Annals of Internal Medicine* Care of the Transgender Patient (2019)
- *Medical News Today* The "Life-Saving" Science Behind Gender Affirming Care for Youth
- HHS guidance on Gender-Affirming Care and Young People and statement in support of LGBTQ+ youth
- Amicus Brief filed by ACP and other medical organizations to Texas Supreme Court

- ACP Statements
  - On Alabama law
  - On Texas directive
  - On Texas, Florida, and Idaho laws

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ACP Journals

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Annals of Internal Medicine

Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians

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Abstract

In this position paper, the American College of Physicians examines the health disparities experienced by the lesbian, gay, bisexual, and transgender (LGBT) community and makes a series of recommendations to achieve equity for LGBT individuals in the health care system. These recommendations include enhancing physician understanding of how to provide culturally and clinically competent care for LGBT individuals, addressing environmental and social factors that can affect their mental and physical well-being, and supporting further research into understanding their unique health needs.

The lesbian, gay, bisexual, and transgender (LGBT) community is diverse, comprising persons from various races, ethnicities, and socioeconomic

backgrounds; however, LGBT persons face a common set of challenges within the health care system. These challenges range from access to health care coverage and culturally competent care to state and federal policies that reinforce social stigma, marginalization, or discrimination. Recent years have brought about reliable data collection, research, and a greater understanding of the health care needs of the LGBT community and the challenges they face in accessing care. Although great strides have been taken in reducing health disparities in the LGBT community, much more needs to be done to achieve equity for LGBT persons in the health care system.

Although members of the LGBT community face similar health concerns as the general population, certain disparities are reported at a higher rate among LGBT persons than the heterosexual population (1). These disparities experienced by LGBT persons may be compounded if they are also part of a racial or ethnic minority (1). Of note, LGBT persons are more likely to identify themselves as being in poor health than heterosexual individuals, and different segments of the LGBT population have individual health risks and needs. For example, gay and bisexual men are at increased risk fo certain sexually transmitted infections and account for more than half of all persons living with HIV or AIDS in the United States (1); lesbian women are less likely to have mammography or Papanicolaou test screening for cancer (2); lesbian and bisexual women are more likely to be overweight or obese (3); and lesbian, gay, and bisexual persons are more likely to become disabled at a younger age than heterosexual individuals (4).

Various state or federal laws may affect the quality of life of LGBT persons and can affect their physical and mental health. Same-sex marriage bans may cause psychological distress (5), prohibitive hospital visitation policies may prevent a same-sex parent from seeing a minor while the child is ill or participating in medical decision making for the child, and exclusions on transgender health care in private and public health plans may cause a transgender patient to seek treatment options through illegal channels (6). These laws and policies, along with others that reinforce marginalization, discrimination, social stigma, or rejection of LGBT persons by their families or communities or that simply keep LGBT persons from accessing health care, have been associated with increased rates of anxiety, suicide, and substance or alcohol abuse (7).

Addressing these disparities will require changes in the way LGBT persons and their families are regarded in society and by the health care system. Policies that are discriminatory toward the LGBT community, or are no longer supported by empirical research, continue to reinforce the environmental and social factors that can affect the mental and physical well-being of LGBT persons. The American College of Physicians (ACP) has a long-standing commitment to improving the health of all Americans and opposes any form of discrimination in the delivery of health care services. ACP is dedicated to eliminating disparities in the quality of or access to health care and is committed to working toward fully understanding the unique needs of the LGBT community and eliminating health disparities for LGBT persons.

This Executive Summary provides a synopsis of the full position paper, which is available in Appendix.

Methods

The ACP Health and Public Policy Committee, which is charged with addressing issues affecting the health care of the U.S. public and the practice of internal medicine and its subspecialties, developed these recommendations. The committee reviewed numerous studies, reports, and surveys on LGBT health care and related health policy. The committee also reviewed information on how state and federal policies may affect the physical and mental health of the LGBT population. Draft recommendations were reviewed by the ACP Board of Regents, Board of Governors, Council of Early Career Physicians, Council of Resident/Fellow Members, Council of Student Members, and Council of Subspecialty Societies. The position paper and recommendations were reviewed by the ACP Board of Regents and approved on 27 April 2015.

ACP Position Statements and Recommendations

The following statements represent the official policy positions and recommendations of the ACP. The rationale for each is provided in the full position paper (Appendix).

A glossary of LGBT terminology used throughout this paper can be found at https://lgbt.ucsf.edu/glossary-terms.

1. The American College of Physicians recommends that gender identity, independent and fundamentally different from sexual orientation, be included as part of nondiscrimination and antiharassment policies. The College encourages medical schools, hospitals, physicians' offices, and other medical facilities to adopt gender identity as part of their nondiscrimination and antiharassment policies.

2. The American College of Physicians recommends that public and private health benefit plans include comprehensive transgender health care services and provide all covered services to transgender persons as they would all other beneficiaries.

3. The definition of "family" should be inclusive of those who maintain an ongoing emotional relationship with a person, regardless of their legal or biological relationship.

4. The American College of Physicians encourages all hospitals and medical facilities to allow all patients to determine who may visit and who may act on their behalf during their stay, regardless of their sexual orientation, gender identity, or marital status, and ensure visitation policies are consisten

the Centers for Medicare & Medicaid Services Conditions of Participation and The Joint Commission standards for Medicare-funded hospitals and critical-access hospitals.

5. The American College of Physicians supports civil marriage rights for same-sex couples. The denial of such rights can have a negative impact on

the physical and mental health of these persons and contribute to ongoing stigma and discrimination for LGBT persons and their families.

6. The American College of Physicians supports data collection and research into understanding the demographics of the LGBT population, potential causes of LGBT health disparities, and best practices in reducing these disparities.

7. Medical schools, residency programs, and continuing medical education programs should incorporate LGBT health issues into their curricula. The College supports programs that would help recruit LGBT persons into the practice of medicine and programs that offer support to LGBT medical students, residents, and practicing physicians.

8. The College opposes the use of "conversion," "reorientation," or "reparative' therapy for the treatment of LGBT persons.

9. The American College of Physicians supports continued reviews of blood donation deferral policies for men who have sex with men. The College supports evidence-based deferral policies that take into account a comprehensive assessment of the risk level of all individuals seeking to donate, which may result in varying deferral periods or a lengthened or permanent deferral on blood donation.

Conclusion

The ACP recognizes that reducing health disparities in the LGBT population will take concerted efforts not only by those in the medical community but

also from society as a whole. Training future physicians to be culturally and clinically competent in LGBT health care, working with practicing physicians to increase their understanding of the LGBT population and their health needs, advocating for practical health policies supported by empirical research, and working to eliminate laws that discriminate against the LGBT community and their families are all important steps to reducing and ultimately eliminating the health disparities experienced by the LGBT community.

Appendix: Lesbian, Gay, Bisexual, and Transgender Health Disparities: A Policy Position Paper From The American College of Physicians

Understanding the LGBT Community

The LGBT community is a highly diverse and multifaceted group of persons encompassing all cultures, ethnicities, and walks of life. Under the LGBT umbrella, each individual group faces unique cultural and health-related needs but shares common challenges, such as social stigma, discrimi and disparities in health care, that unite them.

Research into LGBT health has been expanding as the community has become more visible and outspoken about engaging the health care system in developing a knowledge base on the distinctive challenges and health disparities they face. However, gaps in the medical community's understanding of the overall makeup of the LGBT community and the environmental and social factors that may influence the needs of those

persons present an obstacle to addressing challenges in a meaningful way. In 2011, the Institute of Medicine issued a report outlining a research agenda targeting several areas that could affect how the health care system approaches LGBT health, including demographics, social influences, disparities and inequalities, intervention that includes increasing access to care and addressing physical or mental conditions, and transgender-specific needs. The report also recommended the inclusion of the LGBT community in national health surveys and emphasized a need for scientific rigor and a respectful environment when gathering data (8).

One important obstacle to identifying health issues within the LGBT population is a lack of reliable data and the exclusion of sexual and gender minorities' identification on federal health surveys. Recent efforts have been made to gather population data on persons who identify as lesbian, gay, bisexual, or transgender and those who identify as being in a same-sex marriage or partnership. For the first time in 2010, the U.S. Census Bureau did not change the data reporting the number of same-sex couples that identified as being married. Before that, the 2000 U.S. Census changed the relationship status of same-sex partners identifying as being the spou
the head of household to an "unmarried partner" because there were no states in which same-sex marriage was legal. In the 1990 U.S. Census, if a same-sex couple identified themselves as married, the sex of 1 of the respondents was automatically changed to the opposite sex and the couple was enumerated as an opposite-sex married couple (9). The Patient Protection and Affordable Care Act allows the Department of Health and Human Services (HHS) to collect "additional demographic data to further

improve our understanding of health disparities," and in 2013, the National Health Interview Survey—an annual study of health care access, use, and behaviors—included sexual orientation as part of its data collection system (10). Recent estimates put the number of persons who identify as lesbian, gay, bisexual, or transgender at more than 9 million or approximately 3.4% of the U.S. population, which some analysts believe may be an underestimate (1). Individuals who may have same-sex attractions or experiences but do not self-identify as LGBT may still fall into the category of sexual minorities and face health disparities associated with LGBT persons.

Access to Care in the LGBT Population

The LGBT community has often been overlooked when discussing health care disparities and continues to face barriers to equitable care. Barriers to care are multidimensional and include stigma and discrimination, poverty, lack of education, racial or ethnic minority status, and other psychological health determinants (11). Studies show that persons who identify as LGBT have greater economic disadvantages and are more vulnerable to poverty than those who do not. Using available information from national sur the Williams Institute reports higher overall poverty rates for persons identifying under the LGBT umbrella than heterosexual persons and higher rates of poverty in same-sex couples than heterosexual couples (7.6% vs. 5.7%) (12).

Research shows that LGBT adults and their children are more likely to be uninsured by public or private insurance and that they and their family

members continue to face difficulties in gaining access to care and face a higher risk for health disparities than the general population (2). Most Americans gain health insurance coverage through their employer; data are limited but suggest LGBT persons face higher unemployment rates than non-LGBT persons. A 2009 survey in California found a 14% unemployment rate among LGBT adult workers compared with 10% among non-LGBT adults (13).

The Affordable Care Act sought to increase access to care for low-income Americans by expanding Medicaid programs to all persons at or below 133% of the federal poverty level, providing financial subsidies to help those making between 100% and 400% of the federal poverty level purchase insurance on the federal and state marketplace exchanges, and including nondiscrimination protections in health plans sold on the exchanges. Although estimates suggested that the number of uninsured LGBT persons would be reduced as a result of Medicaid expansion, only about half of states have chosen to expand their Medicaid programs, which greatly diminishes its effect. This increases the number of LGBT persons who may fall into what has been dubbed the "coverage gap," in which persons may earn too m qualify for their state's Medicaid program but too little to qualify for subsidies (14).

Transgender individuals face additional challenges in gaining access to care. Not only are they more likely to be uninsured than the general population, they are more likely to be uninsured than lesbian, gay, or bisexual persons (1). They also face high out-of-pocket costs for transgender-specific medical

care if they lack insurance or their insurance coverage does not cover transgender health care. According to the American Congress of Obstetricians and Gynecologists, transgender youth who receive inadequate treatment are at an increased risk for engaging in self-mutilation or using illicit venues to obtain certain treatments; research shows more than 50% of persons who identify as transgender have obtained injected hormones through illegal means or outside of the traditional medical setting (6).

Mental and Physical Health Disparities

Existing research into the health of the LGBT population has found some health disparities that disproportionately affect the LGBT population. In 2000, the first federally funded research study on the health of LGBT persons assessed 5 major areas of concern for lesbian, gay, and bisexual persons (the report noted that transgender health concerns warranted an independent evaluation): cancer, family planning, HIV and AIDS, immunization and infectious diseases, and mental health (15). Research has shown that lesbian women are less likely to get preventive cancer screenings; lesbian and bisexual women are more likely to be overweight or obese (16); gay m
at higher risk for HIV and other sexually transmitted infections; and LGBT populations have the highest rates of tobacco, alcohol, and other drug use (17). Lesbian, gay, and bisexual persons are approximately 2.5 times more likely to have a mental health disorder than heterosexual men and women (18).

Transgender persons are also at a higher lifetime risk for suicide attempt and show higher incidence of social stressors, such as violence, discrimination, or childhood abuse, than nontransgender persons (19). A 2011 survey of transgender or gender-nonconforming persons found that 41% reported having attempted suicide, with the highest rates among those who faced job loss, harassment, poverty, and physical or sexual assault (20).

Positions

1. The American College of Physicians recommends that gender identity, independent and fundamentally different from sexual orientation, be included as part of nondiscrimination and antiharassment policies. The College encourages medical schools, hospitals, physicians' offices, and other medical facilities to adopt gender identity as part of their nondiscrimination and antiharassment policies.

Nondiscrimination policies are in place to prevent employment discrimination or harassment based on race, color, national or ethnic origin, age, religion, sex, disability, genetics, or other characteristics protecte under federal, state, or local law (21). However, state law varies consic on the inclusion of sexual orientation and gender identity in nondiscrimination policies and some policies based on sexual orientation alone may not include gender identity. Eighteen states have employment nondiscrimination or equal employment opportunity statutes that cover both gender identity and sexual orientation, and an additional 3 states have nondiscrimination statutes that cover sexual orientation only (22). The

Human Rights Campaign, an LGBT rights organization, estimated that as a result of these assorted laws, 3 of 5 U.S. citizens live in an area that does not provide protection for gender identity or sexual orientation (23).

Sexual orientation and gender identity are inherently different and should be considered as such when assessing whether nondiscrimination or harassment policies provide protection to all members of the LGBT community. According to the Institute of Medicine, "sexual orientation" refers to a person's enduring pattern of or disposition to have sexual or romantic desires for, and relationships with, persons of the same sex or both sexes (8). "Gender identity" refers to a person's basic sense of being a man or boy, a woman or girl, or another gender. Gender identity may or may not correspond to a person's anatomical sex assigned at birth. The term "transgender" is now widely used to refer to a diverse group of persons who depart significantly from traditional gender norms (24). Persons who have a "marked difference" between their anatomical sex at birth and their expressed or experienced gender may be diagnosed with gender dysphoria, which is a diagnosis under the American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (25).

Evidence shows that individuals with gender identity variants face increased discrimination, threats of violence, and stigma. The National Gay and Lesbian Task Force and the National Center for Transgender Equality conducted a national survey of transgender and gender-nonidentifying persons and found high rates of harassment (78%), physical assault (35%), and sexual violence (12%) (20). More than 90% of survey participants

reported harassment or discrimination in the workplace, and they experience double the rate of unemployment than the general population (20). Therefore, LGBT persons are more likely to lose their job or not be hired (26).

Employers have the option to include gender identity as part of their company's nondiscrimination or antiharassment policies even if their state does not, and many companies have chosen to include comprehensive protections policies. To reduce the potential for discrimination, harassment, and physical and emotional harm toward persons who are not covered by current protections, the medical community should include both sexual orientation and gender identity as part of any comprehensive nondiscrimination or antiharassment policy.

2. The American College of Physicians recommends that public and private health benefit plans include comprehensive transgender health care services and provide all covered services to transgender persons as they would all other beneficiaries.

The LGBT community is at increased risk for physical and emotional l

resulting from discrimination or harassment, and transgender persons may face greater inequalities in the health care system than the general population. Of note, 19% of transgender persons lack any type of health insurance (20). A handful of states have laws about insurance coverage for transgender health care, such as hormone replacement therapy or sexual reassignment surgery, which may be considered medically necessary as part of the patient's care. Eight states and the District of Columbia have

prohibitions on insurance exclusion of treatments for sex reassignment surgery (27).

The World Professional Association for Transgender Health has developed health care standards for transgender persons who have been diagnosed with gender dysphoria. The standards emphasize treatments that will achieve "lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment" and may or may not include modification to a person's gender expression or how this individual appears or presents physically to others (28). Research shows that when transgender persons receive individual, medically appropriate care, they have improved mental health, reduction in suicide rates, and lower health care costs overall because of fewer mental health–related and substance abuse–related costs (29). However, not all health plans cover all services associated with transgender health or consider such services medically necessary; some plans may issue blanket exclusions on transgender health care, not cover certain services for a transgender person as they would for nontransgender persons, or only cover the cost of gender reassignment surgery if certain conditions are met. For example, an insurance company may cover posthysterectomy estrogenic hormone replacement therapy for biological women but will not cover a similar type of hormone therapy for a postoperative male-to-female transgender patient. Many professional medical organizations, including the American Medical Association, American Psychological Association, American Psychiatric Association, American Congress of Obstetricians and Gynecologists, and

American Academy of Family Physicians, consider gender transition–related medical services medically necessary (30).

The decision to institute a hormone therapy regimen or pursue sexual reassignment surgery for transgender individuals is not taken lightly. Transgender patients and their health care team, which may include primary care physicians, endocrinologists, mental health professionals, and others, are in the best position to determine the most appropriate care plan unique to the patient's needs. Throughout the course of treatment, patients and their physicians or health care team should discuss available options and the evidence base for those treatments in which such evidence exists. It is especially important that transgender patients whose health care team has determined that treatment should include cross-sex hormone therapy or sexual reassignment surgery and postoperative hormone therapy be well-informed about the potential health risks associated with the long-term use of some hormonal replacement therapies before treatment.

Without insurance coverage, the cost of treatment for persons with gender dysphoria may be prohibitively expensive. The most extensive and exp sexual reassignment surgeries may cost tens of thousands of dollars; t does not include associated costs, such as counseling, hormone replacement therapy, copays, or aftercare. The high costs of treatment can result in persons who cannot access the type of care they need, which can increase their levels of stress and discomfort and lead to more serious health conditions. In 2014, the HHS lifted the blanket ban on Medicare coverage for gender reassignment surgery (31) and the federal government announced it

would no longer prohibit health plans offered on the Federal Employees Health Benefits Program from offering gender reassignment as part of the plan (27). Transgender health advocates are hopeful this will result in wider coverage for transgender care in private health plans.

The cost of including transgender health care in employee health benefits plans is minimal and is unlikely to raise costs significantly, if at all. A survey of employers offering transition-related health care in their health benefit plans found that two thirds of employers that provided information on actual costs of employee utilization of transition-related coverage reported 0 costs (32). This is the result of a very small portion of the population identifying as transgender and a smaller portion of that group having the most expensive type of gender reassignment surgery as part of their treatment. An analysis of the utilization of transgender health services over 6 years after transgender discrimination was prohibited in one California health plan found a utilization rate of 0.062 per 1000 covered persons (33). The inclusion of transgender-related health care services within a health plan may also result in an overall reduction of health care costs over time because patients are less likely to engage in self-destructive behaviors, such alcohol or substance abuse.

3. The definition of "family" should be inclusive of those who maintain an ongoing emotional relationship with a person, regardless of their legal or biological relationship.

The term "family" as it is seen in society is changing and no longer means married heterosexual parents with children. An analysis shows only 22% of

families fall into this category (34). Stepparents, single parents, grandparents, same-sex couples, or foster or adoptive parents all make up the changing face of U.S. families. Across the country, LGBT persons are raising children, and demographic data shows that 110 000 same-sex couples are raising as many as 170 000 biological, adopted, or foster children and 37% of LGBT adults have had a child (35). This modern concept of family is no longer dependent on parental status and does not only include adult heads of household with minor children. Same-sex couples and different-sex couples who do not have children may nevertheless have persons in their lives that they consider family.

Despite research that shows a growing trend toward acceptance of LGBT individuals and families (36), there is no widely used standard definition of family inclusive of the diverse nature of the family structure and definitions vary widely: They can differ from state to state, within the Internal Revenue Service for tax purposes, by employers to determine eligibility for health plans, and by hospitals for the purposes of visitation or medical decision making. If LGBT spouses or partners are not legally considered a family member, they are at risk for reduced access to health care and restrict on caregiving and decision making; further, they are at increased risk for health disparities, and their children may not be eligible for health coverage (34). Therefore, LGBT persons and families may already be at a financial disadvantage, with single LGBT parents 3 times more likely to live near the poverty line than their non-LGBT counterparts and LGBT families twice as likely to live near the poverty threshold (35). These financial disadvantages can translate into lack of access to medical care and poorer health outcomes

similar to those experienced by non-LGBT persons and their families who are uninsured or underinsured, in addition to the health disparities that are already reported among the LGBT community.

The Human Rights Campaign's definition of family for health care organizations, developed with multistakeholder input, is inclusive of same- and different-sex married couples and families and is an example of a broad, comprehensive definition of family that includes a person's biological, legal, and chosen family:

> Family means any person(s) who plays a significant role in an individual's life. This may include a person(s) not legally related to the individual. Members of "family" include spouses, domestic partners, and both different-sex and same-sex significant others. "Family" includes a minor patient's parents, regardless of the gender of either parent. (37)

A definition of family inclusive of all types of families, including the LGBT population, is not only fundamental to reducing the disparities and inequalities that exist within the health care system, but also important for the equal treatment of LGBT patients and their visitors in the hospital setting. Countless accounts show loved ones being denied the right to visit; assist in the medical decision-making process for their partner, minor, or child; or be updated on the condition of a patient because hospital visitation policy broadly prohibits those who are not recognized family members from access to the patient. These policies are discriminatory against LGBT patients, their visitors, and the millions of others who are considered family,

such as friends, neighbors, or nonrelative caregivers who can offer support to the patient.

4. The American College of Physicians encourages all hospitals and medical facilities to allow all patients to determine who may visit and who may to act on their behalf during their stay, regardless of their sexual orientation, gender identity, or marital status, and ensure visitation policies are consistent with the Centers for Medicare & Medicaid Services Conditions of Participation and The Joint Commission standards for Medicare-funded hospitals and critical-access hospitals.

When persons or their loved ones need emergency care or extended inpatient stays in the hospital, they do not often immediately think about access to visitors or hospital visitation policies, the ability to assist in medical decision making, or their legal rights as patients or visitors. Hospital visitation policies are not always clear or consistent about who can visit or make medical decisions for a patient if they become incapacitated or cannot do so themselves. The absence or limited access of loved ones can cause uncertainty and anxiety for the patient. In contrast, the involvement c family and outside support systems can improve health outcomes, suc management of chronic illness and continuity of care (38).

A highly publicized incident of LGBT families facing discrimination and being denied hospital visitation occurred in Florida in 2007. A woman on vacation with her family had an aneurysm and was taken to the hospital. Her same-sex partner and their children were denied the right to see her or receive updates on her condition, and she eventually slipped into a coma

and died (39). In response to this incident, President Obama issued a presidential memorandum recommending that the HHS review and update hospital visitation policies for hospitals participating in Medicare or Medicaid and critical-access hospitals to prohibit discrimination based on such factors as sexual orientation or gender identity (40).

Throughout the rulemaking process, the HHS revised the Medicare Conditions of Participation to require that all hospitals explain to all patients their right to choose who may visit during an inpatient stay, including same-sex spouses, domestic partners, and other visitors, and the patients' right to choose a person to act on their behalf. The Joint Commission, the nation's largest organization for hospital accreditation, also updated its standards to include equal visitation for LGBT patients and visitors (41). As a result of these updated policies, most hospitals and long-term care facilities are required to allow equal visitation for LGBT persons and their families.

The presidential memorandum also recommended that the HHS instruct hospitals to disclose to their patients that patients have a right to designate a representative to make medical decisions on their behalf if they cann make those decisions themselves. The revised Conditions of Participa emphasized that hospitals "should give deference to patients' wishes about their representatives, whether expressed in writing, orally, or through other evidence, unless prohibited by state law" (42). With piecemeal regulations and policies governing the legal rights of LGBT persons and their families, some same-sex spouses or domestic partners choose to prepare advance directives, such as durable powers of attorney and health care proxies, in an

effort to ensure their access to family members and their ability to exert their right to medical decision making if necessary.

5. The American College of Physicians supports civil marriage rights for same-sex couples. The denial of such rights can have a negative impact on the physical and mental health of these persons and contribute to ongoing stigma and discrimination for LGBT persons and their families.

The health and financial benefits of marriage for different-sex couples are widely reported, and contemporary research supports similar benefits in same-sex marriage. On the other hand, denial of marriage rights for LGBT persons may lead to mental and physical health problems. Health benefits associated with same-sex marriage result from improved psychological health and a reinforced social environment with community support (43). Research suggests that being in a legally recognized same-sex marriage diminishes mental health differentials between LGBT and heterosexual persons (5). A comparison study on the utilization of public health services by gay and bisexual men before and after Massachusetts legalized same-sex marriage found a reduction in the number of visits for health problen mental health services. The study noted a 13% reduction in visits over after the legalization of same-sex marriage (44).

In contrast, denial of such rights can result in ongoing physical and psychological health issues. Thus, LGBT persons encountering negative societal attitudes and discrimination often internalize stressors and have poor health unseen to those around them; further, these stressors can lead to self-destructive behaviors (43). A study of LGBT individuals living in states

with a same-sex marriage ban found increases in general anxiety, mood disorders, and alcohol abuse (45). The denial of marriage rights to LGBT persons has also been found to reinforce stigmas of the LGBT population that may undermine health and social factors, which can affect young adults (46). The American Medical Association's broad policy supporting civil rights for LGBT persons acknowledges that denial of civil marriage rights can be harmful to LGBT persons and their families and contribute to ongoing health disparities (47).

Since 2003, the overall support for marriage equality has increased. The shift in attitudes toward acceptance of same-sex marriage has broad positive implications for the future of U.S. civil marriage rights. A 2013 survey by the Pew Research Center revealed that nearly half of U.S. adults expressed support for same-sex marriage. Of note, millennials (those born after 1980) showed the highest rate of support for same-sex marriage rights at 70%. Not only has overall opinion changed, but individually, 1 in 7 respondents reported they had changed their minds from opposing to supporting same-sex marriage. The Pew survey found that 32% of respondents changed their mind because they knew someone who identified as lesbian or gay (36

The legal landscape is also shifting in favor of inclusive civil marriage rights for same-sex couples. The American Bar Association has adopted a resolution recognizing "that lesbian, gay, bisexual and transgender (LGBT) persons have a human right to be free from discrimination, threats and violence based on their LGBT status and condemns all laws, regulations and rules or practices that discriminate on the basis that an individual is [an]

LGBT person" (48). In June 2013, the U.S. Supreme Court struck down a provision of the Defense of Marriage Act that defined marriage as a "union between a man and a woman." The decision allowed legally married same-sex couples to have the same federal benefits offered to heterosexual couples (49). Currently more than half of the states and the District of Columbia allow same-sex marriage, and several states have rulings in favor of same-sex marriage that are stayed pending legal appeals (50). In April 2015, the Supreme Court heard oral arguments in a case involving same-sex marriage bans in Michigan, Ohio, Kentucky, and Tennessee; this will ultimately determine the constitutionality of same-sex marriage bans, including whether states would be required to recognize same-sex marriages performed legally out of state (51).

6. The American College of Physicians supports data collection and research into understanding the demographics of the LGBT population, potential causes of LGBT health disparities, and best practices in reducing these disparities.

Previous efforts to understand the LGBT population by including sexu orientation or gender identity in health surveys and data collection ar good first step, but there is a long way to go to understand the unique health needs of all members of the LGBT community. Understanding the demographics of the persons who make up this community is a key first step to understanding how environmental and social determinants may contribute to the health disparities they face. Overwhelming evidence shows that racial and ethnic minorities experience greater health disparities than

the general population. In 2010, ACP published an updated position paper on racial and ethnic disparities in health care, which identified various statistics on health disparities in racial and ethnic minority groups, such as higher levels of uninsured Hispanics than white persons (34% vs. 13%) and lower rates of medication adherence in minority Medicare beneficiaries diagnosed with dementia (52). Persons who are part of both the LGBT community and a racial or ethnic minority group may face the highest levels of disparities. For example, data show that 30% of African American adults who identify as lesbian, gay, or bisexual are likely to delay getting a prescription compared with 19% of African American heterosexual adults (26).

Transgender persons may also face certain increased risk factors that can affect their health that are not included when discussing the LGBT population as a whole, which creates research gaps with the LGBT community. A survey study of transgender persons shows elevated reports of harassment, physical assault, and sexual violence (20). In addition, transgender persons are more likely to face discrimination in education, employment, housing, and public accommodations than other sexual, racial, or ethnic minority groups. The lack of and unfamiliarity with research focused on the physical health issues of transgender persons, such as hormone replacement therapy and cancer risk, limit the understanding or development of best practices that could reduce the disparities felt by this population. The dearth of such research is detrimental to physicians' understanding of issues unique to transgender patients and reduces their ability to care for these patients.

Data that have been gathered in the relatively short time since the inclusion of sexual orientation, gender identity, and same-sex marital status have revealed information that can be used to create tailored plans to decrease health disparities in in the LGBT community. For example, in 2009 the California Health Interview Survey collected information on certain health indicators and included sexual orientation along with racial and minority status. The survey found a higher rate of uninsured lesbian, gay, or bisexual Latino adults in the state than their African American counterparts (36% vs. 14%) (20).

In addition to obtaining information from population surveys, including gender identity and sexual orientation as a component of a patient's medical record (paper or electronic) may help a physician to better understand an LGBT patient's needs and provide more comprehensive care. This can be particularly useful in the care of transgender persons, whose gender identity and gender expression may differ from their sex assigned at birth and are not in line with the standard sex template on many forms. Including this information—especially in electronic health records that can standardize information, such as anatomy present and the preferred name/pronou can create a more comfortable experience for the patient and keep the physician up to date on the patient's transition history, if applicable (53). If a physician uses paper medical records, the patient's chart should be flagged using an indicator, such as a sticker, to alert staff to use the preferred name and pronoun of the patient (54).

7. Medical schools, residency programs, and continuing medical education programs should incorporate LGBT health issues into their curricula. The College supports programs that would help recruit LGBT persons into the practice of medicine and programs that offer support to LGBT medical students, residents, and practicing physicians.

Establishing understanding, trust, and communication between a physician and a patient is key to an ongoing and beneficial physician–patient relationship. However, reported instances of physician bias or denial of care to LGBT patients may influence patients to withhold information on their sexual orientation, gender identity, or medical conditions that could help the physician have a better understanding of the potential health needs of their patients. Physicians can play an integral role in helping an LGBT patient navigate through the medical system by providing respectful, culturally, and clinically competent care that underscores the overall health of the patient. In an article published in *The New England Journal of Medicine,* Makadon noted how physicians can create a welcoming and inclusive environment to LGBT patients:

> [G]uidelines for clinical practice can be very simple: ask the appropri[illegible] questions and be open and nonjudgmental about the answers. Few patients expect their providers to be experts on all aspects of gay and lesbian life. But it is important that providers inquire about life situations, be concerned about family and other important relationships, understand support systems, and make appropriate referrals for counseling and support when necessary. (55)

Providing clinically and culturally competent care for transgender persons in the primary care setting may present a challenge to physicians who are not knowledgeable about transgender health. Transgender persons have reported encounters with physicians who are unaware of how to approach treatment of a transgender person, and half of transgender patients reported having to "teach" their physician about transgender health (20). The National Transgender Survey found that 19% of participants had been denied medical care because of their transgender status (20). Resources for physicians on how to approach the treatment of transgender patients should emphasize respecting the patient's gender identity while providing prevention, treatment, and screening to the anatomy that is present (56).

To better understand the unique health needs of the LGBT community, physicians and medical professionals must develop a knowledge base in cultural and clinical competency and understand the factors that affect LGBT health; this should begin in the medical school setting and continue during practice. Assessment of LGBT-related content at medical schools found a median of 5 hours spent on LGBT-related issues over the course of the curriculum (57). Exposure to members of the LGBT population in medical school has been shown to increase the likelihood that a physician will take a more comprehensive patient history, have a better understanding of LGBT health issues, and have a more positive attitude toward LGBT patients (58). Studies show that undergraduate students pursuing a career in medicine are receptive to incorporating LGBT-related issues into their education and agree that it applies to their future work (59). The College recognizes the importance of incorporating LGBT health into the medical

school curriculum and publishes a comprehensive medical textbook on LGBT health, *The Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health, 2nd Edition* (60).

In November 2014, the Association of American Medical Colleges Advisory Committee on Sexual Orientation, Gender Identity, and Sex Development released a comprehensive report recommending strategies on how to implement changes in academic medical institutions to better address the needs of LGBT patients; further, the committee identified challenges and barriers to carrying out these changes. The report recognizes 3 methods of integrating LGBT health into the medical school curricula: full curriculum revision, the addition of a required class, or LGBT health study as a part of elective materials. The report also identifies barriers to curricular changes, including but not limited to a lack of material that has been shown to be effective, reluctance of faculty and staff to teach the new material, and a shortage of institutional time that would permit teachers to participate in continuing education on the topic (61).

For some LGBT persons interested in pursuing careers in medicine, th continues to be an underlying concern that their sexual orientation or gender identity may affect their selection into a medical school or residency program and acceptance by their peers. In 2012, Dr. Mark Schuster published his personal story about being gay in medicine starting in the 1980s when he entered medical school, through residency, and into practice. In his article, he spoke of a former attending physician he worked under who acted as an advisor and had indicated he would offer him a

recommendation for residency, only to find this physician later renege on that offer after Dr. Schuster shared that he was gay (62). Little research has been done on the recruitment of LGBT physicians into the practice of medicine or how disclosing sexual orientation may affect training. One survey measuring the perceptions and attitudes toward sexual orientation during training found that 30% of respondents did not reveal their sexual orientation when applying for residency positions for fear of rejection (63).

Academic medical institutions can make efforts to create a welcoming and inclusive environment for students and faculty. The University of California, San Francisco, LGBT Resource Center developed a checklist for medical schools to assess LGBT curriculum, admissions, and the working environment within their institution. The checklist includes inclusive application procedures, measurement of retention of LGBT students, and efforts and resources dedicated to student well-being (64). In a 2013 white paper, the Gay and Lesbian Medical Association made several recommendations to support an LGBT-inclusive climate at health professional schools in such areas as institutional equality, transgender services and support, diversity initiatives, admissions, staff and facult recruitment and retention, staff and faculty training, and other areas that underscore simple yet thoughtful ways to create an accepting environment for LGBT students, faculty, and employees (65). Tools such as these can assist in recruiting and retaining LGBT physicians.

8. The College opposes the use of "conversion," "reorientation," or "reparative' therapy for the treatment of LGBT persons.

Since 1973, the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* has not considered homosexuality an illness (66). All major medical and mental health organizations do not consider homosexuality as an illness but as a variation of human sexuality, and they denounce the practice of reparative therapy for treatment of LGBT persons (67). The core basis for "conversion," "reorientation," or "reparative" therapy, which is generally defined as therapy aiming at changing the sexual orientation of lesbian women and gay men, is mostly based on religious or moral objections to homosexuality or the belief that a homosexual person can be "cured" of their presumed illness.

In 2007, the American Psychological Association conducted a literature review of 83 studies on the efficacy of efforts to change sexual orientation. It found serious flaws in the research methods of most of the studies and identified only 1 study that met research standards for establishing safety or efficacy of conversion therapy and also compared persons who received a treatment with those who did not. In that study, intervention had no effect on the rates of same-sex behavior, so it is widely believed that there is no scientific evidence to support the use of reparative therapy (68). The I PDF Help American Health Organization, the regional office for the Americas of the larger World Health Organization, also supports the position that there is no medical basis for reparative therapy and that the practice may pose a threat to the overall health and well-being of an individual (69). Dr. Robert Spitzer, the author of a 2003 research study often cited by supporters of the reparative therapy movement to purport that persons may choose to change their sexual orientation, has denounced the research as flawed and

apologized to the LGBT community in a letter for misinterpretations or misrepresentations that arose from the study (70).

Available research does not support the use of reparative therapy as an effective method in the treatment of LGBT persons. Evidence shows that the practice may actually cause emotional or physical harm to LGBT individuals, particularly adolescents or young persons. Research done at San Francisco State University on the effect of familial attitudes and acceptance found that LGBT youth who were rejected by their families because of their identity were more likely than their LGBT peers who were not rejected or only mildly rejected by their families to attempt suicide, report high levels of depression, use illegal drugs, or be at risk for HIV and sexually transmitted illnesses (71). The American Psychological Association literature review found that reparative therapy is associated with the loss of sexual feeling, depression, anxiety, and suicidality (68).

States have delved into the debate over the use of reparative therapy for minor children given the potential for harm. California; New Jersey; and Washington, DC, have enacted laws banning the practice. Several othe legislatures, such as those in Washington state, Massachusetts, New Y and Oregon, have introduced or passed legislation through one chamber but failed to pass the bill into law (72). The New Jersey law was challenged on the grounds that the ban limited the free speech of mental health professionals, but the law was upheld by the Third U.S. Circuit Court of Appeals (73). In May 2015, the U.S. Supreme Court declined to hear a challenge to the law (74).

9. The American College of Physicians supports continued reviews of blood donation deferral policies for men who have sex with men. The College supports evidence-based deferral policies that take into account a comprehensive assessment of the risk level of all individuals seeking to donate, which may result in varying deferral periods or a lengthened or permanent deferral on blood donation.

Persons who are considered at increased or possible risk for certain infectious diseases, such as intravenous drug users, recipients of animal organs or tissues, and those who have traveled or lived abroad in certain countries, are prohibited by the U.S Food and Drug Administration from donating blood (75). Since the early 1980s, the policy has also included men who have sex with men (MSM) since 1977. This lifetime deferral of blood donation for MSM was instituted during a time when the incidence of HIV and AIDS increased to epidemic levels in the United States, and the disease and how it was transmitted were largely misunderstood by the scientific community. In the following years, concerted efforts by the medical community, patient advocates, and government officials and agencies resulted in advancements in blood screening technology and treatmei the virus. However, during that time of uncertainty, policies were implemented to balance the risk for contaminating the blood supply with what was known about the transmissibility of the disease.

Several medical organizations support deferral policy reform based on available scientific evidence and testing capabilities. The American Medical Association policy on blood donor criteria supports, "the use of rational,

scientifically based blood and tissue donation deferral periods that are fairly and consistently applied to donors according to their level of risk" (76). The American Association of Blood Banks, America's Blood Centers, and the American Red Cross have long advocated for a modification to deferral criteria to be "made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections" and recommend a 12-month deferral for men who have had sex with another man since 1977, which is in line with deferral criteria for others who have exhibited high-risk behavior (77). The eligibility standards and policies on the donation of tissues or tissue products (5-year deferral since last sexual contact) (78) and vascular organs (risk assessed individually, disclosed to transplant team, and consent required) (79) by MSM also reflect a measured assessment of disease transmission risk to donor recipients.

Many countries, including the United Kingdom, Canada, Finland, Australia, and New Zealand, have successfully instituted deferral periods ranging from 12 months to 5 years in lieu of a lifetime ban on blood donation by MSM without measurable increased risk to the blood supply. A study of the risk of blood donations from MSM after the implementation of shorter defer periods in England and Wales 12 months after their last sexual encounter found only a marginal increase in the risk for transfusion-transmitted HIV (80). Australia changed the deferral policy for MSM from 5 years to 12 months over 1996 to 2000. A study that compared the prevalence of HIV among blood donors from the 5-year deferral period compared with the 12-month deferral period found no evidence that the 12-month period increased risk for HIV in recipients (81).

In late 2014, the HHS Advisory Committee on Blood and Tissue Safety and Availability voted in favor of recommending a 1-year deferral policy for MSM and increased surveillance of the blood supply. The U.S Food and Drug Administration announced it would be updating its policy on blood donation from MSM after considering recommendations made by the HHS, reviews of available scientific evidence, and recommendations from its own Blood Products Advisory Committee. The policy about indefinite deferral on blood donation from MSM is being updated to a 1-year deferral period from the last sexual contact, and the U.S. Food and Drug Administration will issue draft guidance on the policy change in 2015. In addition, the agency announced it has already taken steps to implement a national blood surveillance system to monitor what, if any, effects the new policy has on the nation's blood supply (82). Lifting the lifetime ban on blood donation by MSM is an important first step toward creating equity among those wishing to donate blood. The U.S Food and Drug Administration should continue to monitor the effects of a 1-year deferral and update its policy as information and data are gathered through surveillance to make further strides toward policies that assess donor eligibility on the basis of scientific data and individual risk fact such as the length of time since a high-risk behavior has occurred, typ sex that occurred, number of partners during a period of time, or a combination of factors (83).

Comments

6 Comments

Rex Moss, MD • Dallas, Texas • 27 May 2015

Comment

To the Editor: "ACP Takes a Stand against Health Disparities Affecting LGBT Individuals New policy paper aims to ensure high-quality health care for all" This is very disappointing. I love the Annals and very much enjoyed and learned a great deal at several ACP conferences. But I left the AMA as it stood up for abortion rights and I resign from ACP, now as you stand up for a number of foolish policies, more oriented to political ideology than medical care or logic. Your new policy states: For instance, health data related to marital status show a benefit for married heterosexual couples, but the committee found that the fact that LGBT partners and families live without the same protections and recognition appears to increase their risk for depression and other poor health outcomes. Does it really follow that societys protections and encouragement of heterosexual marriage has the power to prevent depression and poor health outcomes? Is it possible that heterosexual marriage is our natural state and that our minds and bodies work best when used in the appropriate way? ACP's Health and Public Policy Committee recommends: Including comprehensive transgender heath care services in public and private health benefit plans. You recommend public and private insurance pay for sexual reassignment surgery. Is there data of benefit? Perhaps a reduction in mortality, disability or morbidity? Do those who have sexual reassignment surgery live longer or commit suicide less often? Why should anyone outside the person determined to change their body pay for it? Expanding the definition of "family" to include all who maintain an emotional connection to the patient, regardless of legal or biological relationship. Do you have data that children raised in families other than with their biological parents do better or as well? In absence of data, would it not be logical to encourage keeping biological parents together or at least permit states to make the judgment for themselves how to regulate/ encourage marriage? (as opposed to having courts take over as the "determiners of all things not established by study or fact") Opposing the use of "conversion," "reorientation" or "reparative" therapies in the treatment of LGBT individuals. Do you have data that such therapies are harmful? If a deeply disturbed person is confused about his/ her sexual identity and wants to focus attention on the opposite sex and seeks counseling to do so, is that wrong or harmful? LGBT individuals have a high incidence of depression and suicide. Do you wish to oppose possible the may help if you have no alternative therapy that will help? Political trends come and go. Slavery, racial marriage, cocaine, smoking, breast self-exam, and epinephrine have been normal, encouraged, discouraged and tossed away. Allowing a popular political idea to lead to policy changes not supported by data, that costs a great deal of money and is very disruptive to a current healthy institution: heterosexual marriage is a poor plan. ACP think before you act. When you act wrongly think again and change. Good-bye, Rex Moss MD

Hilary Daniel, BS, Renee Butkus, BA • American College of Physicians • 11 September 2015

Response to Comments Made by Drs. Lacy and Ng

The two comments submitted by Drs. Lacy and Ng speak to the diversity of ACP's 143,000 internal medicine physicians and student members. ACP advocates on a wide variety of topics and the College

recognizes that not all ACP members will agree with our positions. The need to address the unique needs of the LGBT persons and their families is a based on ACP's long standing commitment to advocate for those being negatively affected by health care disparities. Ignoring or glossing over some topics that affect health because they are controversial would be inconsistent with ACP's mission "To enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine" including "to advocate responsible positions on individual health and on public policy relating to health care for the benefit of the public, our patients, the medical profession, and our members."

We appreciate Dr. Ng's support for our paper. As the paper was being developed, policies concerning same sex marriage, blood donation by men who have sex with men, and coverage for transgender health care services were undergoing change. The College recognizes the need for continued review of issues relating to LGBT health.

Dr. Lacy takes issue with our call for a more inclusive definition of family. As our paper points out, it's estimated that only 22% of U.S. families consist of married heterosexual parents with their own biological children. A modern definition of family that is inclusive of all types of families, including the LGBT population, is fundamental to reducing the disparities and inequalities that exist within the health care system and to equal treatment of LGBT patients and their visitors in the hospital setting. Our opposition to "therapy" to change the sexual orientation of an individual is based on the science that shows that sexual and gender orientation are not disability or disorder in need of treatment or cure, and that such "therapies" may be harmful to patients receiving them.

Hilary Daniel, BS
Renee Butkus, BA

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Paul J Hudson, MD, MPH, FACP • SIM • 22 June 2015

The policy on LGBT reaches beyond evidence

Dear friends at ACP,

I too am disappointed at the lack of evidence for this very broad set of policy changes, which not only goes beyond the evidence but becomes an agent for changing institutions that have stood the test of millenia. For example, defining a family as something other than biological is a step in the wrong direction. The evidence shows that children need a father and they need a mother; this has something to do with biology, and cannot be socially constructed.

Please reconsider your over-reach and return to medical evidence.

Thank you,

Paul Hudson, MD, FACP, MPH

Mark D Lacy • Lubbock, Tx • 3 June 2015

Access for All but losing our way in the Process

To advocate for the elimination of health care disparities among Lesbian, Gay, Bisexual, and Transgender (LGBT) persons is a worthy objective not just for these populations but all patients facing obstacles to quality care. Sadly, the American College of Physicians Position Paper published May 12, 2015 addressing LGBT Health Disparities goes beyond advocating health care access by promoting a damaging sociopolitical ideology. The Paper re-defines the meaning of family, marriage, and calls for denying LGBT persons choices in behavioral health services.

While alleging the Position Paper was the product following review of "numerous studies, reports, and surveys on LGBT health care and related health policy" many cited references are based on research neither well executed nor widely corroborated. Further, it appears the reviewers fail to account for sound, copious evidence contradicting the cited sources.

To redefine family as "those who maintain an ongoing emotional relationship with a person, regardless of their legal or biological relationship" is to deny the reality of paternity and maternity, both integr most wholesome child-rearing environments. Dads contribute to the growth and development children much differently than moms do. Asserting family as whatever one wants it to be is to succumb to the solipsistic notion that the self is the final arbiter of reality, to substitute the real and immutable childhood need for mothers and fathers with the sexual-romantic mutable desires of adults. Will the next Position Paper call for endorsing the aims of the North American Man Boy Love Association or Peter Singer's call for granting civil rights to primates? Marriage is, and for millennia has been, rooted in the male-female complementarity that makes sexual reproduction possible and child-rearing wholistic. What is at play in this Statement are very imprudent mental maneuvres, "The moment you step into the world of facts, you step into a world of limits. You can free things from alien or accidental laws, but not from the laws of their own nature. You may, if you like, free a tiger from his bars, but not free him from his stripes. Do not free a camel from his hump; you may be freeing him from being a camel". In "re-inventing" family and the meaning of marriage is to engage in the same sort of casuistry.

With regard to the American Psychological Association (APA) being invoked as the authority to repudiate psychotherapy for unwanted sexual behaviours recall the APA Task Force unequivocally posits "Same-sex sexual attractions, behavior, and orientations per se are normal and positive variants of human sexuality." If that is the a priori assertion, can objective assessment of "sexual orientation change efforts" (SOCE) be realistically expected? Probably not. To satisfactorily debunk SOCE entails more than citing the APA. In the meantime, persons who opt for SOCE should be given the prerogative in the same way, for example, the transgender person is offered high- dose estrogens in spite of the increased risk of thrombosis.

The LGBT Position Papers unfortunately makes the Annals a mouthpiece for the post-modern notion that we can write our own narrative and call it true, regardless of the facts. Once the Annals becomes a purveyor of ideology and asserts a world view which doesn't comport with facts, it is no longer a reliable source of guidance for physicians.

Mark D Lacy, MD, MA, FACP

Henry Ng, MD, MPH, FAAP, FACP • **MetroHealth Medical Center, Case Western Reserve** University School of Medicine • 2 June 2015

In support of the American College of Physician's Policy Position Paper on Lesbian, Gay, Bisexual and Transgender Health Disparities

As an internist-pediatrician who has worked in LGBT health care for the last decade, I am invigorated that the American College of Physicians (ACP), one of my professional homes, has developed a set of LGBT health focused policy statements. From my perspective as an LGBT health advocate and clinical director of a hospital-based LGBT health service line, these policy statements were sorely needed to assist internists around the US and internationally to improve the health experiences and outcomes, and ultimately eliminate health disparities of LGBT patients. I am proud to see the American College of Physicians join a growing group of professional organizations with LGBT-inclusive policies or mi: statements including the American Academy of Family Physicians, the American Medical Assoc American Academy of Pediatrics, the American Academy of Physician Assistants, the American Academy of Nursing , the American College of Obstetrics and Gynecology, the American Psychological Association, the American Psychiatric Association, GLMA: Health Professionals Advancing LGBT Equality and others.

The nine policy statements developed by Daniel et al which compose the ACP's policy position paper are both bold and broad in their recommendations. Many of the recommendations are timely and remind internists to keep in-step with guidelines set forth by accrediting bodies such as the Joint Commission and the Centers for Medicare & Medicaid Services. This is especially important as more and more LGBT Americans enroll in health insurance through the Affordable Care Act and begin to routinely access the US health care system. However, the ACP's policy statements will only be as useful as they are complete and current and must be considered a living document with the capacity to grow and change based on

the best available data and knowledge regarding LGBT health. I encourage the members of the ACP Health and Public Policy Committee to revisit the policy statement on regular intervals for updates to fill the many gaps in our knowledge about LGBT health.

Future revisions of the policy statement should pay careful attention to details not necessarily called out in the current policy's executive summary. For example, policy statement 2 calls for the ACP to "recommend that all public and private health benefit plans include comprehensive transgender care services and provide all covered services to transgender persons as they would all other beneficiaries."1 The authors continue to describe the impact of arbitrary or blanket exclusions for transgender health services in their example of hysterectomy coverage for a cisgender patient, but exclusion for a transgender patient. Yet in the policy statement, the ACP falls short of stating that such hormonal and/or surgical care is medically necessary. Moreover, the term "comprehensive" is an unclear term in this context. For optimal health outcomes, comprehensive care would need to be inclusive of all medically necessary care including primary care, mental health care, transgender hormonal care, transgender-related and non-transgender-related surgical care, and HIV care.

The policy authors write in policy statement 6 that the ACP supports data collection and research into the understanding the demographics of the LGBT population, potential causes of LGBT health disparities, and best practices in reducing these disparities. This statement particularly important as there exist few nationally representative datasets describing LGBT population health. In fact, Healthy People 2020 still prioritizes collecting data on LGB and Transgender populations in their four objectives.2 To date, only the 2013 National Health Interview Survey has collected nationally representative data on lesbian, gay and bisexual people.3 Federal nationally representative surveys continue to exclude transgender respondents by not collecting gender identity/expression as part of the respondents' demographic variables. Unfortunately, the majority of electronic health records also fail to provide fields for collection of sexual orientation and gender identity (SOGI) data. Cahill et al found that integrating SOGI data collection into the meaningful use requirements was both acceptable to diverse samples of patients, including heterosexuals, and feasible.4 The ACP should consider supporting inclusion of SOGI data collection in Meaningful Use as another strategy to improve LGBT health data collection.

Daniel et al write in position statement 7 that "Medical Schools, residency programs, and continue medical education programs should incorporate LGBT health issues into their curriculum. The College supports programs that would help recruit LGBT persons into the practice of medicine and programs that offer support to other LGBT medical students, residents, and practicing physicians."1 Creating the next generation of culturally and clinically competent health professionals and internists is central to improving LGBT health. Nationally, few health organizations and hospitals have actively implemented comprehensive programs to create LGBT affirming environments, educate health professionals and staff on LGBT health, or create sustainable supportive infrastructure. There continues to be a great need for LGBT safe space programs, LGBT 101 cultural competency education, and inclusion of LGBT topics in academic discourse and mentorship. Homophobia, transphobia, few visible LGBT health professional

mentors and lack of institutional support for LGBT health scholarship serve as barriers to growing a cadre of academic internists adequately prepared to care for LGBT populations.5 The College can continue to champion LGBT health by supporting inclusion of LGBT health content in internal medicine certification examination questions, internal medicine in-training examination questions and promotion of additional LGBT health education resources like Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health.6

Finally, the ACP should consider adding an additional statement which addresses and acknowledges the intersectionality of our patients' identities as noted by IOM report.7 Sexual orientation and gender identity/expression do not exist within a vacuum and are part of the multidimensionality of our identities as people.

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Disclosures: I am the President of GLMA: Health Professionals Advancing LGBT Equality

Hilary Daniel • American College of Physicians • 13 May 2015

FDA Releases Draft Guidance on Blood Donation by MSM

On Tuesday May 12, 2015 the Food and Drug Administration released the document "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Draft Guidance for Industry." The proposed recommendations would replace the lifetime deferral period on blood donation by men who have sex with men (MSM) with a 12-month deferral period from most recent sexual contact. The FDA is accepting public comment on the guidance for 60 days.

PREVIOUS ARTICLE NEXT ARTICLE

TAB 176-2

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
jamo.madara@ama-assn.org

Pl. Trial Ex. 042

April 26, 2021

Mr. Bill McBride
Executive Director
National Governors Association
Hall of States
444 North Capitol Street NW, Suite 267
Washington, DC 20001

Dear Mr. McBride:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to urge the National Governors Association (NGA) and its member governors to oppose state legislation that would prohibit the provision of medically necessary gender transition-related care to minor patients. We believe this legislation represents a dangerous governmental intrusion into the practice of medicine and will be detrimental to the health of transgender children across the country.

Empirical evidence has demonstrated that trans and non-binary gender identities are normal variations of human identity and expression. For gender diverse individuals, standards of care and accepted medically necessary services that affirm gender or treat gender dysphoria may include mental health counseling, non-medical social transition, gender-affirming hormone therapy, and/or gender-affirming surgeries. Clinical guidelines established by professional medical organizations for the care of minors promote these supportive interventions based on the current evidence and that enable young people to explore and live the gender that they choose. Every major medical association in the United States recognizes the medical necessity of transition-related care for improving the physical and mental health of transgender people.

Arkansas' recently enacted SAFE Act and similar bills pending in several other states would insert the government into clinical decision-making and force physicians to disregard clinical guidelines. Decisions about medical care belong within the sanctity of the patient-physician relationship. As with all medical interventions, physicians are guided by their ethical duty to act in the best interest of their patients and must tailor recommendations about specific interventions and the timing of those interventions to each patient's unique circumstances. Such decisions must be sensitive to the child's clinical situation, nurture the child's short and long-term development, and balance the need to preserve the child's opportunity to make important life choices autonomously in the future. We believe it is inappropriate and harmful for any state to legislatively dictate that certain transition-related services are never appropriate and limit the range of options physicians and families may consider when making decisions for pediatric patients.

In addition, evidence has demonstrated that forgoing gender-affirming care can have tragic consequences. Transgender individuals are up to three times more likely than the general population to report or be diagnosed with mental health disorders, with as many as 41.5 percent reporting at least one diagnosis of a mental health or substance use disorder.[1] The increased prevalence of these mental health conditions is widely thought to be a consequence of minority stress, the chronic stress from coping with societal

[1] Sari Reisner, et al., *Psychiatric Diagnoses and Comorbidities in a Diverse, Multicity Cohort of Young Transgender Women: Baseline Findings from Project LifeSkills*, 170 J. Am. Med. Ass'n Pediatrics 5, 481–86 (May 2016).

stigma, and discrimination because of one's gender identity and expression. Because of this stress, transgender minors also face a significantly heightened risk of suicide.

Transgender children, like all children, have the best chance to thrive when they are supported and can obtain the health care they need. Studies suggest that improved body satisfaction and self-esteem following the receipt of gender-affirming care is protective against poorer mental health and supports healthy relationships with parents and peers.[2] Studies also demonstrate dramatic reductions in suicide attempts, as well as decreased rates of depression and anxiety.[3] Other studies show that a majority of patients report improved mental health and function after receipt of gender-affirming care. Medically supervised care can also reduce rates of harmful self-prescribed hormones, use of construction-grade silicone injections, and other interventions that have potential to cause adverse events.[4]

It is imperative that transgender minors be given the opportunity to explore their gender identity under the safe and supportive care of a physician. Arkansas's law and others like it would forestall that opportunity. This is a dangerous intrusion into the practice of medicine and we strongly urge the NGA and its member governors to oppose these troubling bills.

We thank you for the opportunity to express our views on this important issue. Please contact Annalia Michelman, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at annalia.michelman@ama-assn.org to discuss this issue further and how our two organizations can work together.

Sincerely,

James L. Madara, MD

[2] Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J Sexual Med 4, 591-600 (Apr. 2018); Michelle Marie Johns, et al., *Protective Factors Among Transgender and Gender Variant Youth: A Systematic Review by Socioecological Level*, 39 J Primary Prevention 3, 263-301 (Jun. 2018).

[3] M. Hassan Murad, et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 Clinical Endocrinology 2, 214-331 (Feb. 2010); Yolanda Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adult and Adolescent Transsexuals*, 35 Psychological Med. 1, 89-99 (Jan. 2005).

[4] Jessica Xavier, Admin. HIV and AIDS, D.C. Gov't, The Washington Transgender Needs Assessment Survey (2000); Wendy Bostwick & Gretchen Kenagy, *Health and Social Service Needs of Transgendered People in Chicago*, 8 Int'l J Transgenderism 2-3, 57-66 (Oct. 2008); Cathy Reback, et al., Los Angeles Transgender Health Study: Community Report (2001).

TAB 176-3

ISSUE BRIEF

Health insurance coverage for gender-affirming care of transgender patients

Background

Gender identity refers to an individual's concept of self as male, female, a blend of both or neither. Approximately 1.4 million adults and 150,000 youth ages 13 to 17 in the United States identify as transgender, meaning those individuals' gender identity and/or expression is different from cultural expectations based on the sex they were assigned at birth.[1] Individuals may also identify as gender expansive, meaning they identify with neither traditional binary gender role nor a single gender narrative or experience.[2] In this document, the term transgender is used inclusive of patients with transgender or gender expansive identities.

Many but not all transgender people experience gender dysphoria, a medical condition defined by the American Psychiatric Association as a "conflict between a person's physical or assigned gender and the gender with which he/she/they identify."[3] Standards of care and accepted medically necessary services that affirm gender or treat gender dysphoria may include but are not limited to mental health counseling, non-medical social transition, gender-affirming hormone therapy, and/or gender-affirming surgeries.[4] Every major medical association in the United States recognizes the medical necessity of transition-related care for improving the physical and mental health of transgender people and has called for health insurance coverage for treatment of gender dysphoria.[5]

Barriers to care

As a population, transgender individuals are frequently subject to bias and discrimination in many aspects of their lives, including the provision of health care. The transgender population is less likely to be insured than both the lesbian, gay and bisexual (LGB) and general populations and often faces challenges in accessing needed healthcare services.[6] A national survey of transgender individuals found:

- 25 percent of respondents experienced a problem with their insurance in the past year related to being transgender, such as being denied coverage for care related to gender transition;
- 25 percent of those who sought coverage for hormones in the past year were denied;
- 55 percent of those who sought coverage for transition-related surgery in the past year were denied;

1. Andrew Flores et al., Williams Inst., UCLA Sch. of Law, How Many Adults Identify as Transgender in the United States? (2016).
2. Joel Baum, et al., Human Rights Campaign & Gend. Spectrum, Supporting and Caring for our Gender Expansive Youth (2013).
3. *What Is Gender Dysphoria?*, Am. Psychiatric Ass'n, https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria
4. World Professional Ass'n for Transgender Health, Standards of Care Version 7 (2018), *available at* https://www.wpath.org/publications/soc; Wylie Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An *Endocrine Society Clinical Practice Guideline*, 102 J Clinical Endocrinology & Metabolism 11, 3869-903 (Sep. 2017); Eli Coleman, et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7*, 13 Int'l J Transgenderism 4, 165-232 (Aug. 2012).
5. Kellan Baker, *The Future of Transgender Coverage*, 376 New Eng. J. Med. 19, 1801-04 (May 2017).
6. Jen Kates, et al., Henry J. Kaiser Family Found., Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the US, issue brief, May 2018; Sandy James, et al., Nat'l Ctr. Transgender Equality, The Report of the 2015 US Transgender Survey (2016); U.S. Census Bureau, 2015 American Community Survey 1-Year Estimates (2015), *available at* https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_1YR_S2701&prodType=table.

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- 78 percent of respondents wanted hormone therapy related to gender transition, but only 49 percent had ever received it;
- 42 percent reported that insurance covered only some of the surgical care needed for transition; and
- 21 percent reported that insurance covered transition-related surgery, but had no in-network providers.[7]

Federal and state policies

Section 1557 of the Affordable Care Act (ACA) created specific protections barring insurance discrimination based on sexual orientation and gender identity.[8] Prior to enactment, medically necessary gender-affirming hormones and surgeries were often excluded from insurance coverage. Addressing this disparity, the US Department of Health and Human Services (HHS) promulgated final regulations in 2016 implementing section 1557 of the ACA to extend protections against sex discrimination to health coverage and care for the first time and including gender identity discrimination within the definition of sex discrimination.[9] However, a federal court stayed a legal challenge to the rule after the current Administration announced it would reconsider the rule's prohibition on discrimination based on gender identity. The timeline for HHS reconsideration is unknown and the current Administration has, to date, declined to defend the regulation.[10] Rulings by the Equal Employment Opportunity Commission remain intact, however, which found that employer-sponsored plans that exclude gender-affirming care violate Title VII.[11] Title VII of the Civil Rights Act prohibits employment discrimination based on race, color, religion, sex and national origin.

In addition to the ACA, the federal government has taken steps to bar discrimination against transgender individuals in federal health programs. In 2014, HHS invalidated a prior prohibition on Medicare coverage of gender-affirming surgery, citing evidence supporting its effectiveness in treating gender dysphoria and potential for improved health outcomes.[12] In 2016, the federal Office of Personnel Management barred exclusions for gender transition services from the Federal Employees Health Benefits Program. In 2018, the US Department of Veterans Affairs (VA) proposed to amend its medical regulations by removing a provision that excludes "gender alterations" from its medical benefits package, which would effectively authorize transition-related surgery as part of VA care when medically necessary. Final regulations, however, have not yet been issued by the VA.

State-wise, twenty states (CA, CT, CO, DE, HI, IL, MA, MD, MI, MN, NJ, NM, NV, NY, OR, PA, RI, VT and WA) and District of Columbia prohibit health insurers from excluding coverage for transgender health services.[13] California, for example, prohibits health plans from denying coverage or limiting coverage on the basis of sex, which is defined to include gender, gender identity and gender expression. In regulation, California specifies four prohibited practices:

- Denying or cancelling an insurance policy on the basis of gender identity;
- Using gender identity as a basis for determining premium;
- Considering gender identity as a pre-existing condition; and
- Denying coverage or claims for health care services to transgender people when coverage is provided to non-transgender people for the same services.[14]

7. Nat'l Ctr. Transgender Equality, The Report of the 2015 US Transgender Survey (2016)
8. 42 U.S.C. § 18116.
9. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375 (May 18, 2016) (to be codified in 45 C.F.R. pt. 92).
10. *Franciscan Alliance, Inc. et al. v. Burwell et al.*, No. 7:16–cv-00108-o (N.D. Texas Dec. 31, 2016).
11. *Macy v. Holder*, No. 0120120821, 2012 WL 1435995 (E.E.O.C. Apr. 20, 2012); *EEOC v. Deluxe Financial Services Corp.*, (D. Minn., Civ. No. 0:15-cv-02646-ADM-SER, filed June 4, 2015, settled January 20, 2016).
12. U.S. Dep't Health & Human Servs., Departmental Appeals Bd., Appellate Div. NCD 140.3, Transsexual Surgery, Docket No. A-13–87, Decision No. 2576 (May 30, 2014).
13. Baker, *supra* note 5.
14. Cal. Ins. Code § 10140; Cal. Code Regs. Tit. 10 § 2561.2.

Cost savings

In promulgating the regulations, the California Department of Insurance issued an Economic Impact Assessment that determined that aggregate costs of the antidiscrimination rules would be "insignificant and immaterial" while yielding significant benefits to transgender individuals including suicide reduction, improvements in mental health, reduction in substance use rates, higher rates of adherence to HIV care and reduction in self-medication.[15] The Economic Impact Assessment also identified potential cost savings in the medium to long term due to lower costs associated with suicide, attempts at suicide, overall improvements in mental health and lower rates of substance abuse.[16] The assessment noted that the Centers for Disease Control and Prevention estimate the average acute medical costs of a single suicide completion or attempt in the United States is $2,596 and $7,234 respectively.[17]

Other studies have similarly demonstrated that transgender inclusive health coverage is cost-effective compared to the costs associated with untreated gender dysphoria.[18] A cost analysis of the City and County of San Francisco's coverage of transition-related surgeries found that costs in the first five years to both insurers and employers were low, averaging between $0.77 and $0.96 per year per enrollee, and resulted in no surcharge or premium increases.[19] The analysis also found no evidence of a "magnet effect" wherein transgender individuals would have deliberately sought employment in order to access services.

Health implications for transgender individuals

Transgender individuals in the US are up to three times more likely than the general population to report or be diagnosed with mental health disorders, with as many as 41.5 percent reporting at least one diagnosis of a mental health or substance use disorder:

- Over a third of transgender individuals suffer a major depressive episode in their lifetimes;
- 20.2 percent have been diagnosed with suicidality in the past 30 days;
- 7.9 percent have been diagnosed with an anxiety disorder in the past six months;
- 9.8 percent have been diagnosed with post-traumatic stress disorder in the past six months; and
- 15.2 percent have been diagnosed with a substance use disorder in the past year.[20]

The increased prevalence of these mental health conditions is widely thought to be a consequence of minority stress, the chronic stress from coping with societal stigma and discrimination because of one's gender identity and expression.[21] Indeed, gender based discrimination affecting access to services is a strong predictor of suicide risk among transgender persons.[22] Lack of access to gender-affirming care may directly contribute to poor mental

15. State of Cal., Dep't Ins., Economic Impact Assessment, Gender Nondiscrimination in Health Insurance, Reg-2011-00023 (Apr. 13, 2012).
16. *Id.*
17. *Id*, citing Ctrs. Disease Control & Prevention, Nat'l Ctr. Injury Prevention & Control, Fact Sheet: The Medical Cost Associated with Suicide in the United States, 2010.
18. State of Cal., supra note 15; William Padula, et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis*, 31 J Gen. Internal Med. 4, 394-401 (Apr. 2016).
19. Human Rights Campaign, San Francisco Transgender Benefit, available at http://www.hrc.org/resources/san-francisco-transgender-benefit
20. Sari Reisner, et al., *Psychiatric Diagnoses and Comorbidities in a Diverse, Multicity Cohort of Young Transgender Women: Baseline Findings from Project LifeSkills*, 170 J. Am. Med. Ass'n Pediatrics 5, 481–86 (May 2016).
21. Stephen Russell & Jessica Fish, *Mental Health in Lesbian, Gay, Bisexual, and Transgender (LGBT) Youth*, 12 Ann. Rev. Clinical Psychology 1, 465-87 (Mar. 2016).
22. Kristin Clements-Nolle, et al., *Attempted Suicide among Transgender Persons: The Influence of Gender-Based Discrimination and Victimization*, 53 J Homosexuality 3, 53-69 (Oct. 2008).

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health: individuals with gender dysphoria who have undergone no gender confirmation treatment are twice as likely to experience moderate to severe depression and four times more likely to experience anxiety than their surgically-affirmed peers.[23]

Improving access to gender-affirming care is an important means of improving health outcomes for the transgender population. Studies demonstrate dramatic reductions in rate of suicide attempts, with one meta-analysis finding that suicidality rates dropped from 30 percent pre-treatment to 8 percent post-treatment.[24] Studies have also demonstrated a decrease in depression and anxiety and that a majority of patients report improved mental health and function after receipt of gender-affirming care.[25] In addition, receipt of appropriate care is associated with decreased substance use and improved HIV medication adherence among the transgender population, reducing long term negative health outcomes and potential transmission rates. [26] Medically supervised care can also reduce rates of harmful self-prescribed hormones, use of construction grade silicone injections and other interventions that have potential to cause adverse events.[27]

Patients who receive gender-affirming care, including surgical care, feel more congruent in their bodies and report improved mental health. Specifically, one study found that facial feminization surgery improved mental health-related quality of life scores among transgender women to levels seen in the general female population.[28] Studies suggest that improved body satisfaction and self-esteem following medical and surgical therapies is protective against poorer mental health and also supports healthy relationships with parents and peers.[29]

Positive health effects from gender-affirming care extend to children and adolescents as well.[30] Recent research demonstrates that integrated affirmative models of care for youths, which include access to medications and surgeries, result in fewer mental health concerns than has been historically seen among transgender populations.[31] Importantly, rates of self-reported feelings of regret among adolescents following receipt of gender-affirming care are extremely low.[32]

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23. Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J Sexual Med 4, 591-600 (Apr. 2018).
24. M. Hassan Murad, et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 Clinical Endocrinology 2, 214-331 (Feb. 2010).
25. Yolanda Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adult and Adolescent Transsexuals*, 35 Psychological Med. 1, 89-99 (Jan. 2005); Tiffany Ainsworth & Jeffrey Spiegel, *Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery*, 19 Quality Life Res. 7, 1019-24 (Sep. 2010).
26. Jamil Rehman, et al., *The Reported Sex and Surgery Satisfactions of 28 Postoperative Male to-Female Transsexual Patients*, 28 Archives Sexual Behav. 1, 71-89; Jae Sevelius, Adam Carrico & Mallory Johnson, *Antiretroviral Therapy Adherence Among Transgender Women Living with HIV*, 21 J Ass'n Nurses AIDS Care 3, 256-64 (May 2010).
27. Jessica Xavier, Admin. HIV and AIDS, D.C. Gov't, The Washington Transgender Needs Assessment Survey (2000); Wendy Bostwick & Gretchen Kenagy, *Health and Social Service Needs of Transgendered People in Chicago*, 8 Int'l J Transgenderism 2-3, 57-66 (Oct. 2008); Cathy Reback, et al., Los Angeles Transgender Health Study: Community Report (2001).
28. Ainsworth & Spiegel, *supra* note 25.
29. Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J Sexual Med 4, 591-600 (Apr. 2018); Michelle Marie Johns, et al., *Protective Factors Among Transgender and Gender Variant Youth: A Systematic Review by Socioecological Level*, 39 J Primary Prevention 3, 263-301 (Jun. 2018).
30. Lily Durwood, Katie Mclaughlin & Kristina Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth*, 56 J Am Acad. Child Adolescent Psychiatry 2, 116-23 (Nov. 2016).
31. Laura Edwards-Leeper & Norman Spack, *Psychological evaluation and medical treatment of transgender youth in an interdisciplinary "Gender Management Service" (GeMS) in a major pediatric center*, 59 J Homosexuality 3, 321-36 (Mar. 2012). Edgardo Menvielle, *A comprehensive program for children with gender variant behaviors and gender identity disorders*, 59 J Homosexuality 3, 357-68 (Mar. 2012); Darryl Hill, et al., *An affirmative intervention for families with gender variant children: parental ratings of child mental health and gender*, 36 J Sex & Marital Therapy 1, 6–23 (2010)
32. Johanna Olson-Kennedy, et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 5, 431-436 (May 2018).

Medical society opinions

The AMA opposes any discrimination based on an individual's sex, sexual orientation or gender identity, opposes the denial of health insurance on the basis of sexual orientation or gender identity, and supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. GLMA: Health Professionals Advancing LGBTQ Equality recognizes that mental healthcare, hormone replacement therapy, and/or gender-affirming surgery are medically necessary for the treatment of transgender people who meet the criteria for gender dysphoria and advocates that these services not be excluded from any public or private insurance programs. In addition, other medical associations, including the American Academy of Family Physicians, American College of Obstetricians and Gynecologists and American Psychiatric Association have stated that medically necessary transition-related care should be covered by insurance.[33]

AMA policy

Removing Financial Barriers to Care for Transgender Patients H-185.950
Our AMA supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (Res. 122 A-08; Modified: Res. 05, A-16)

Sexual Orientation and/or Gender Identity as Health Insurance Criteria H-180.980
The AMA opposes the denial of health insurance on the basis of sexual orientation or gender identity. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97; Reaffirmed: CMS Rep. 9, A-07; Modified: BOT Rep. 11, A-07; Reaffirmed: CMS Rep. 01, A-17)

Military Medical Policies Affecting Transgender Individuals H-40.966
Our American Medical Association affirms that there is no medically valid reason to exclude transgender individuals from service in the US military and affirms transgender service members be provided care as determined by patient and physician according to the same medical standards that apply to non-transgender personnel. (Res. 11, A-15)

Reducing Suicide Risk Among Lesbian, Gay, Bisexual, Transgender, and Questioning Youth Through Collaboration with Allied Organizations H-60.927
Our AMA will partner with public and private organizations dedicated to public health and public policy to reduce lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth suicide and improve health among LGBTQ youth. (Res. 402, A-12)

GLMA policy

GLMA 127-18-101: Transgender Healthcare
Therapeutic treatment, including hormone therapy, mental health therapy and gender affirming surgeries, are medically necessary for the treatment of gender dysphoria. These gender-affirming medical and surgical treatments should be covered by all public and private insurance plans. (Approved 2018)

For additional information or assistance with advocacy to protect transgender individuals' access to medically necessary services, please visit the www.ama-assn.org/go/arc or contact Annalia Michelman, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at annalia.michelman@ama-assn.org or (312) 464-4788.

33. See Am. Acad. Fam. Physicians, Coverage Equity for Drugs, Testing, Procedure, Preventive Services, and Reproductive Technologies (2017); Am. College Obstetricians & Gynecologists, Health Care for Transgender Individuals (2011); Am. Psychiatric Ass'n, Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012).

TAB 176-5

Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

American Psychological Association

Transgender and gender nonconforming[1] (TGNC) people are those who have a gender identity that is not fully aligned with their sex assigned at birth. The existence of TGNC people has been documented in a range of historical cultures (Coleman, Colgan, & Gooren, 1992; Feinberg, 1996; Miller & Nichols, 2012; Schmidt, 2003). Current population estimates of TGNC people have ranged from 0.17 to 1,333 per 100,000 (Meier & Labuski, 2013). The Massachusetts Behavioral Risk Factor Surveillance Survey found 0.5% of the adult population aged 18 to 64 years identified as TGNC between 2009 and 2011 (Conron, Scott, Stowell, & Landers, 2012). However, population estimates likely underreport the true number of TGNC people, given difficulties in collecting comprehensive demographic information about this group (Meier & Labuski, 2013). Within the last two decades, there has been a significant increase in research about TGNC people. This increase in knowledge, informed by the TGNC community, has resulted in the development of progressively more trans-affirmative practice across the multiple health disciplines involved in the care of TGNC people (Bockting, Knudson, & Goldberg, 2006; Coleman et al., 2012). Research has documented the extensive experiences of stigma and discrimination reported by TGNC people (Grant et al., 2011) and the mental health consequences of these experiences across the life span (Bockting, Miner, Swinburne Romine, Hamilton, & Coleman, 2013), including increased rates of depression (Fredriksen-Goldsen et al., 2014) and suicidality (Clements-Nolle, Marx, & Katz, 2006). TGNC people's lack of access to trans-affirmative mental and physical health care is a common barrier (Fredriksen-Goldsen et al., 2014; Garofalo, Deleon, Osmer, Doll, & Harper, 2006; Grossman & D'Augelli, 2006), with TGNC people sometimes being denied care because of their gender identity (Xavier et al., 2012).

In 2009, the American Psychological Association (APA) Task Force on Gender Identity and Gender Variance (TFGIGV) survey found that less than 30% of psychologist and graduate student participants reported familiarity with issues that TGNC people experience (APA TFGIGV, 2009). Psychologists and other mental health professionals who have limited training and experience in TGNC-affirmative care may cause harm to TGNC people (Mikalson, Pardo, & Green, 2012; Xavier et al., 2012). The significant level of societal stigma and discrimination that TGNC people face, the associated mental health consequences, and psychologists' lack of familiarity with trans-affirmative care led the APA Task Force to recommend that psychological practice guidelines be developed to help psychologists maximize the effectiveness of services offered and avoid harm when working with TGNC people and their families.

Purpose

The purpose of the *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* (hereafter *Guidelines*) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people. Trans-affirmative practice is the provision

The American Psychological Association's (APA's) Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming People developed these guidelines. lore m. dickey, Louisiana Tech University, and Anneliese A. Singh, The University of Georgia, served as chairs of the Task Force. The members of the Task Force included Walter O. Bockting, Columbia University; Sand Chang, Independent Practice; Kelly Ducheny, Howard Brown Health Center; Laura Edwards-Leeper, Pacific University; Randall D. Ehrbar, Whitman Walker Health Center; Max Fuentes Fuhrmann, Independent Practice; Michael L. Hendricks, Washington Psychological Center, P.C.; and Ellen Magalhaes, Center for Psychological Studies at Nova Southeastern University and California School of Professional Psychology at Alliant International University.

The Task Force is grateful to BT, Robin Buhrke, Jenn Burleton, Theo Burnes, Loree Cook-Daniels, Ed Delgado-Romero, Maddie Deutsch, Michelle Emerick, Terry S. Gock, Kristin Hancock, Razia Kosi, Kimberly Lux, Shawn MacDonald, Pat Magee, Tracee McDaniel, Edgardo Menvielle, Parrish Paul, Jamie Roberts, Louise Silverstein, Mary Alice Silverman, Holiday Simmons, Michael C. Smith, Cullen Sprague, David Whitcomb, and Milo Wilson for their assistance in providing important input and feedback on drafts of the guidelines. The Task Force is especially grateful to Clinton Anderson, Director, and Ron Schlittler, Program Coordinator, of APA's Office on LGBT Concerns, who adeptly assisted and provided counsel to the Task Force throughout this project. The Task Force would also like to thank liaisons from the APA Committee on Professional Practice and Standards (COPPS), April Harris-Britt and Scott Hunter, and their staff support, Mary Hardiman. Additionally, members of the Task Force would like to thank the staff at the Phillip Rush Center and Agnes Scott College Counseling Center in Atlanta, Georgia, who served as hosts for face-to-face meetings.

This document will expire as APA policy in 2022. After this date, users should contact the APA Public Interest Directorate to determine whether the guidelines in this document remain in effect as APA policy.

Correspondence concerning this article should be addressed to the Public Interest Directorate, American Psychological Association, 750 First Street, NE, Washington, DC 20002.

[1] For the purposes of these guidelines, we use the term *transgender and gender nonconforming* (TGNC). We intend for the term to be as broadly inclusive as possible, and recognize that some TGNC people do not ascribe to these terms. Readers are referred to Appendix A for a listing of terms that include various TGNC identity labels.

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of care that is respectful, aware, and supportive of the identities and life experiences of TGNC people (Korell & Lorah, 2007). The *Guidelines* are an introductory resource for psychologists who will encounter TGNC people in their practice, but can also be useful for psychologists with expertise in this area of practice to improve the care already offered to TGNC people. The *Guidelines* include a set of definitions for readers who may be less familiar with language used when discussing gender identity and TGNC populations (see Appendix A). Distinct from TGNC, the term "cisgender" is used to refer to people whose sex assigned at birth is aligned with their gender identity (E. R. Green, 2006; Serano, 2006).

Given the added complexity of working with TGNC and gender-questioning youth[2] and the limitations of the available research, the *Guidelines* focus primarily, though not exclusively, on TGNC adults. Future revisions of the *Guidelines* will deepen a focus on TGNC and gender-questioning children and adolescents. The *Guidelines* address the strengths of TGNC people, the challenges they face, ethical and legal issues, life span considerations, research, education, training, and health care. Because issues of gender identity are often conflated with issues of gender expression or sexual orientation, psychological practice with the TGNC population warrants the acquisition of specific knowledge about concerns unique to TGNC people that are not addressed by other practice guidelines (APA, 2012). It is important to note that these *Guidelines* are not intended to address some of the conflicts that cisgender people may experience due to societal expectations regarding gender roles (Butler, 1990), nor are they intended to address intersex people (Dreger, 1999; Preves, 2003).

Documentation of Need

In 2005, the APA Council of Representatives authorized the creation of the Task Force on Gender Identity and Gender Variance (TFGIGV), charging the Task Force to review APA policies related to TGNC people and to offer recommendations for APA to best meet the needs of TGNC people (APA TFGIGV, 2009). In 2009, the APA Council of Representatives adopted the Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination, which calls upon psychologists in their professional roles to provide appropriate, nondiscriminatory treatment; encourages psychologists to take a leadership role in working against discrimination; supports the provision of adequate and necessary mental and medical health care; recognizes the efficacy, benefit, and medical necessity of gender transition; supports access to appropriate treatment in institutional settings; and supports the creation of educational resources for all psychologists (Anton, 2009). In 2009, in an extensive report on the current state of psychological practice with TGNC people, the TFGIGV determined that there was sufficient knowledge and expertise in the field to warrant the development of practice guidelines for TGNC populations (APA TFGIGV, 2009). The report identified that TGNC people constituted a population with unique needs and that the creation of practice guidelines would be a valuable resource for the field (APA TFGIGV, 2009). Psychologists' relative lack of knowledge about TGNC people and trans-affirmative care, the level of societal stigma and discrimination that TGNC people face, and the significant mental health consequences that TGNC people experience as a result offer a compelling need for psychological practice guidelines for this population.

Users

The intended audience for these *Guidelines* includes psychologists who provide clinical care, conduct research, or provide education or training. Given that gender identity issues can arise at any stage in a TGNC person's life (Lev, 2004), clinicians can encounter a TGNC person in practice or have a client's presenting problem evolve into an issue related to gender identity and gender expression. Researchers, educators, and trainers will benefit from use of these *Guidelines* to inform their work, even when not specifically focused on TGNC populations. Psychologists who focus on TGNC populations in their clinical practice, research, or educational and training activities will also benefit from the use of these *Guidelines*.

Distinction Between Standards and Guidelines

When using these *Guidelines*, psychologists should be aware that APA has made an important distinction between *standards* and *guidelines* (Reed, McLaughlin, & Newman, 2002). Standards are mandates to which all psychologists must adhere (e.g., the *Ethical Principles of Psychologists and Code of Conduct*; APA, 2010), whereas guidelines are aspirational. Psychologists are encouraged to use these *Guidelines* in tandem with the *Ethical Principles of Psychologists and Code of Conduct*, and should be aware that state and federal laws may override these *Guidelines* (APA, 2010).

In addition, these *Guidelines* refer to psychological practice (e.g., clinical work, consultation, education, research, and training) rather than treatment. Practice guidelines are practitioner-focused and provide guidance for professionals regarding "conduct and the issues to be considered in particular areas of clinical practice" (Reed et al., 2002, p. 1044). Treatment guidelines are client-focused and address intervention-specific recommendations for a clinical population or condition (Reed et al., 2002). The current *Guidelines* are intended to complement treatment guidelines for TGNC people seeking mental health services, such as those set forth by the World Professional Association for Transgender Health Standards of Care (Coleman et al., 2012) and the Endocrine Society (Hembree et al., 2009).

[2] For the purposes of these guidelines, "youth" refers to both children and adolescents under the age of 18.

Compatibility

These *Guidelines* are consistent with the APA *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010), the *Standards of Accreditation for Health Service Psychology* (APA, 2015), the APA TFGIGV (2009) report, and the APA Council of Representatives Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination (Anton, 2009).

Practice Guidelines Development Process

To address one of the recommendations of the APA TFGIGV (2009), the APA Committee on Sexual Orientation and Gender Diversity (CSOGD; then the Committee on Lesbian, Gay, Bisexual, and Transgender Concerns) and Division 44 (the Society for the Psychological Study of Lesbian, Gay, Bisexual and Transgender Issues) initiated a joint Task Force on Psychological Practice Guidelines with Transgender and Gender Nonconforming People in 2011. Task Force members were selected through an application and review process conducted by the leadership of CSOGD and Division 44. The Task Force included 10 members who had substantial psychological practice expertise with TGNC people. Of the 10 task force members, five individuals identified as TGNC with a range of gender identities and five identified as cisgender. In terms of race/ethnicity, six of the task force members identified as White and four identified as people of color (one Indian American, one Chinese American, one Latina American, and one mixed race).

The Task Force conducted a comprehensive review of the extant scholarship, identified content most pertinent to the practice of psychology with TGNC people, and evaluated the level of evidence to support guidance within each guideline. To ensure the accuracy and comprehensiveness of these *Guidelines*, Task Force members met with TGNC community members and groups and consulted with subject matter experts within and outside of psychology. When the Task Force discovered a lack of professional consensus, every effort was made to include divergent opinions in the field relevant to that issue. When this occurred, the Task Force described the various approaches documented in the literature. Additionally, these *Guidelines* were informed by comments received at multiple presentations held at professional conferences and comments obtained through two cycles of open public comment on earlier *Guideline* drafts.

This document contains 16 guidelines for TGNC psychological practice. Each guideline includes a Rationale section, which reviews relevant scholarship supporting the need for the guideline, and an Application section, which describes how the particular guideline may be applied in psychological practice. The *Guidelines* are organized into five clusters: (a) foundational knowledge and awareness; (b) stigma, discrimination, and barriers to care; (c) life span development; (d) assessment, therapy, and intervention; and (e) research, education, and training.

Funding for this project was provided by Division 44 (Society for the Psychological Study of LGBT Issues); the APA Office on Lesbian, Gay, Bisexual, and Transgender (LGBT) Concerns; a grant from the Committee on Division/APA Relations (CODAPAR); and donations from Randall Ehrbar and Pamela St. Amand. Some members of the Task Force have received compensation through presentations (e.g., honoraria) or royalties (e.g., book contracts) based in part on information contained in these *Guidelines*.

Selection of Evidence

Although the number of publications on the topic of TGNC-affirmative practice has been increasing, this is still an emerging area of scholarly literature and research. When possible, the Task Force relied on peer-reviewed publications, but books, chapters, and reports that do not typically receive a high level of peer review have also been cited when appropriate. These sources are from a diverse range of fields addressing mental health, including psychology, counseling, social work, and psychiatry. Some studies of TGNC people utilize small sample sizes, which limits the generalizability of results. Few studies of TGNC people utilize probability samples or randomized control groups (e.g., Conron et al., 2012; Dhejne et al., 2011). As a result, the Task Force relied primarily on studies using convenience samples, which limits the generalizability of results to the population as a whole, but can be adequate for describing issues and situations that arise within the population.

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Rationale. Gender identity is defined as a person's deeply felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; or an alternative gender (Bethea & McCollum, 2013; Institute of Medicine [IOM], 2011). In many cultures and religious traditions, gender has been perceived as a binary construct, with mutually exclusive categories of male or female, boy or girl, man or woman (Benjamin, 1966; Mollenkott, 2001; Tanis, 2003). These mutually exclusive categories include an assumption that gender identity is always in alignment with sex assigned at birth (Bethea & McCollum, 2013). For TGNC people, gender identity differs from sex assigned at birth to varying degrees, and may be experienced and expressed outside of the gender binary (Harrison, Grant, & Herman, 2012; Kuper, Nussbaum, & Mustanski, 2012).

Gender as a nonbinary construct has been described and studied for decades (Benjamin, 1966; Herdt, 1994; Kulick, 1998). There is historical evidence of recognition, societal acceptance, and sometimes reverence of diversity in gender identity and gender expression in several different cultures (Coleman et al., 1992; Feinberg, 1996; Miller

& Nichols, 2012; Schmidt, 2003). Many cultures in which gender nonconforming persons and groups were visible were diminished by westernization, colonialism, and systemic inequity (Nanda, 1999). In the 20th century, TGNC expression became medicalized (Hirschfeld, 1910/1991), and medical interventions to treat discordance between a person's sex assigned at birth, secondary sex characteristics, and gender identity became available (Meyerowitz, 2002).

As early as the 1950s, research found variability in how an individual described their[3] gender, with some participants reporting a gender identity different from the culturally defined, mutually exclusive categories of "man" or "woman" (Benjamin, 1966). In several recent large online studies of the TGNC population in the United States, 30% to 40% of participants identified their gender identity as other than man or woman (Harrison et al., 2012; Kuper et al., 2012). Although some studies have cultivated a broader understanding of gender (Conron, Scout, & Austin, 2008), the majority of research has required a forced choice between man and woman, thus failing to represent or depict those with different gender identities (IOM, 2011). Research over the last two decades has demonstrated the existence of a wide spectrum of gender identity and gender expression (Bockting, 2008; Harrison et al., 2012; Kuper et al., 2012), which includes people who identify as either man or woman, neither man nor woman, a blend of man and woman, or a unique gender identity. A person's identification as TGNC can be healthy and self-affirming, and is not inherently pathological (Coleman et al., 2012). However, people may experience distress associated with discordance between their gender identity and their body or sex assigned at birth, as well as societal stigma and discrimination (Coleman et al., 2012).

Between the late 1960s and the early 1990s, health care to alleviate gender dysphoria largely reinforced a binary conceptualization of gender (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). At that time, it was considered an ideal outcome for TGNC people to conform to an identity that aligned with either sex assigned at birth or, if not possible, with the "opposite" sex, with a heavy emphasis on blending into the cisgender population or "passing" (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). Variance from these options could raise concern for health care providers about a TGNC person's ability to transition successfully. These concerns could act as a barrier to accessing surgery or hormone therapy because medical and mental health care provider endorsement was required before surgery or hormones could be accessed (Berger et al., 1979). Largely because of self-advocacy of TGNC individuals and communities in the 1990s, combined with advances in research and models of trans-affirmative care, there is greater recognition and acknowledgment of a spectrum of gender diversity and corresponding individualized, TGNC-specific health care (Bockting et al., 2006; Coleman et al., 2012).

Application. A nonbinary understanding of gender is fundamental to the provision of affirmative care for TGNC people. Psychologists are encouraged to adapt or modify their understanding of gender, broadening the range of variation viewed as healthy and normative. By understanding the spectrum of gender identities and gender expressions that exist, and that a person's gender identity may not be in full alignment with sex assigned at birth, psychologists can increase their capacity to assist TGNC people, their families, and their communities (Lev, 2004). Respecting and supporting TGNC people in authentically articulating their gender identity and gender expression, as well as their lived experience, can improve TGNC people's health, well-being, and quality of life (Witten, 2003).

Some TGNC people may have limited access to visible, positive TGNC role models. As a result, many TGNC people are isolated and must cope with the stigma of gender nonconformity without guidance or support, worsening the negative effect of stigma on mental health (Fredriksen-Goldsen et al., 2014; Singh, Hays, & Watson, 2011). Psychologists may assist TGNC people in challenging gender norms and stereotypes, and in exploring their unique gender identity and gender expression. TGNC people, partners, families, friends, and communities can benefit from education about the healthy variation of gender identity and gender expression, and the incorrect assumption that gender identity automatically aligns with sex assigned at birth.

Psychologists may model an acceptance of ambiguity as TGNC people develop and explore aspects of their gender, especially in childhood and adolescence. A nonjudgmental stance toward gender nonconformity can help to counteract the pervasive stigma faced by many TGNC people and provide a safe environment to explore gender identity and make informed decisions about gender expression.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Rationale. The constructs of gender identity and sexual orientation are theoretically and clinically distinct, even though professionals and nonprofessionals frequently conflate them. Although some research suggests a potential link in the development of gender identity and sexual orientation, the mechanisms of such a relationship are unknown (Adelson & American Academy of Child and Adolescent Psychiatry [AACAP] Committee on Quality Issues [CQI], 2012; APA TFGIGV, 2009; A. H. Devor, 2004; Drescher & Byne, 2013). *Sexual orientation* is defined as a person's sexual and/or emotional attraction to another person (Shively & De Cecco, 1977), compared with *gender identity*, which is defined by a person's felt, inherent sense of gender. For most people, gender identity develops earlier than sexual orientation. Gender identity is often established in young toddlerhood (Adelson & AACAP CQI, 2012; Kohlberg, 1966), compared with aware-

[3] The third person plural pronouns "they," "them," and "their" in some instances function in these guidelines as third-person singular pronouns to model a common technique used to avoid the use of gendered pronouns when speaking to or about TGNC people.

ness of same-sex attraction, which often emerges in early adolescence (Adelson & AACAP CQI, 2012; D'Augelli & Hershberger, 1993; Herdt & Boxer, 1993; Ryan, 2009; Savin-Williams & Diamond, 2000). Although gender identity is usually established in childhood, individuals may become aware that their gender identity is not in full alignment with sex assigned at birth in childhood, adolescence, or adulthood. The developmental pathway of gender identity typically includes a progression through multiple stages of awareness, exploration, expression, and identity integration (Bockting & Coleman, 2007; A. H. Devor, 2004; Vanderburgh, 2007). Similarly, a person's sexual orientation may progress through multiple stages of awareness, exploration, and identity through adolescence and into adulthood (Bilodeau & Renn, 2005). Just as some people experience their sexual orientation as being fluid or variable (L. M. Diamond, 2013), some people also experience their gender identity as fluid (Lev, 2004).

The experience of questioning one's gender can create significant confusion for some TGNC people, especially for those who are unfamiliar with the range of gender identities that exist. To explain any discordance they may experience between their sex assigned at birth, related societal expectations, patterns of sexual and romantic attraction, and/or gender role nonconformity and gender identity, some TGNC people may assume that they must be gay, lesbian, bisexual, or queer (Bockting, Benner, & Coleman, 2009). Focusing solely on sexual orientation as the cause for discordance may obscure awareness of a TGNC identity. It can be very important to include sexual orientation and gender identity in the process of identity exploration as well as in the associated decisions about which options will work best for any particular person. In addition, many TGNC adults have disguised or rejected their experience of gender incongruence in childhood or adolescence to conform to societal expectations and minimize their fear of difference (Bockting & Coleman, 2007; Byne et al., 2012).

Because gender and patterns of attraction are used to identify a person's sexual orientation, the articulation of sexual orientation is made more complex when sex assigned at birth is not aligned with gender identity. A person's sexual orientation identity cannot be determined by simply examining external appearance or behavior, but must incorporate a person's identity and self-identification (Broido, 2000).

Application. Psychologists may assist people in differentiating gender identity and sexual orientation. As clients become aware of previously hidden or constrained aspects of their gender identity or sexuality, psychologists may provide acceptance, support, and understanding without making assumptions or imposing a specific sexual orientation or gender identity outcome (APA TFGIGV, 2009). Because of their roles in assessment, treatment, and prevention, psychologists are in a unique position to help TGNC people better understand and integrate the various aspects of their identities. Psychologists may assist TGNC people by introducing and normalizing differences in gender identity and expression. As a TGNC person finds a comfortable way to actualize and express their gender identity, psychologists may notice that previously incongruent aspects of their sexual orientation may become more salient, better integrated, or increasingly egosyntonic (Bockting et al., 2009; H. Devor, 1993; Schleifer, 2006). This process may allow TGNC people the comfort and opportunity to explore attractions or aspects of their sexual orientation that previously had been repressed, hidden, or in conflict with their identity. TGNC people may experience a renewed exploration of their sexual orientation, a widened spectrum of attraction, or a shift in how they identify their sexual orientation in the context of a developing TGNC identity (Coleman, Bockting, & Gooren, 1993; Meier, Pardo, Labuski, & Babcock, 2013; Samons, 2008).

Psychologists may need to provide TGNC people with information about TGNC identities, offering language to describe the discordance and confusion TGNC people may be experiencing. To facilitate TGNC people's learning, psychologists may introduce some of the narratives written by TGNC people that reflect a range of outcomes and developmental processes in exploring and affirming gender identity (e.g., Bornstein & Bergman, 2010; Boylan, 2013; J. Green, 2004; Krieger, 2011; Lawrence, 2014). These resources may potentially aid TGNC people in distinguishing between issues of sexual orientation and gender identity and in locating themselves on the gender spectrum. Psychologists may also educate families and broader community systems (e.g., schools, medical systems) to better understand how gender identity and sexual orientation are different but related; this may be particularly useful when working with youth (Singh & Burnes, 2009; Whitman, 2013). Because gender identity and sexual orientation are often conflated, even by professionals, psychologists are encouraged to carefully examine resources that claim to provide affirmative services for lesbian, gay, bisexual, transgender, and queer (LGBTQ) people, and to confirm which are knowledgeable about and inclusive of the needs of TGNC people before offering referrals or recommendations to TGNC people and their families.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Rationale. Gender identity and gender expression may have profound intersections with other aspects of identity (Collins, 2000; Warner, 2008). These aspects may include, but are not limited to, race/ethnicity, age, education, socioeconomic status, immigration status, occupation, disability status, HIV status, sexual orientation, relational status, and religion and/or spiritual affiliation. Whereas some of these aspects of identity may afford privilege, others may create stigma and hinder empowerment (Burnes & Chen, 2012; K. M. de Vries, 2015). In addition, TGNC people who transition may not be prepared for changes in privilege or societal treatment based on gender identity and gender expression. To illustrate, an African American trans man may gain male privilege, but may face racism and

societal stigma particular to African American men. An Asian American/Pacific Islander trans woman may experience the benefit of being perceived as a cisgender woman, but may also experience sexism, misogyny, and objectification particular to Asian American/Pacific Islander cisgender women.

The intersection of multiple identities within TGNC people's lives is complex and may obstruct or facilitate access to necessary support (A. Daley, Solomon, Newman, & Mishna, 2008). TGNC people with less privilege and/or multiple oppressed identities may experience greater stress and restricted access to resources. They may also develop resilience and strength in coping with disadvantages, or may locate community-based resources available to specific groups (e.g., for people living with HIV; Singh et al., 2011). Gender identity affirmation may conflict with religious beliefs or traditions (Bockting & Cesaretti, 2001). Finding an affirmative expression of their religious and spiritual beliefs and traditions, including positive relationships with religious leaders, can be an important resource for TGNC people (Glaser, 2008; Porter, Ronneberg, & Witten, 2013; Xavier, 2000).

Application. In practice, psychologists strive to recognize the salient multiple and intersecting identities of TGNC people that influence coping, discrimination, and resilience (Burnes & Chen, 2012). Improved rapport and therapeutic alliance are likely to develop when psychologists avoid overemphasizing gender identity and gender expression when not directly relevant to TGNC people's needs and concerns. Even when gender identity is the main focus of care, psychologists are encouraged to understand that a TGNC person's experience of gender may also be shaped by other important aspects of identity (e.g., age, race/ethnicity, sexual orientation), and that the salience of different aspects of identity may evolve as the person continues psychosocial development across the life span, regardless of whether they complete a social or medical transition.

At times, a TGNC person's intersection of identities may result in conflict, such as a person's struggle to integrate gender identity with religious and/or spiritual upbringing and beliefs (Kidd & Witten, 2008; Levy & Lo, 2013; Rodriguez & Follins, 2012). Psychologists may aid TGNC people in understanding and integrating identities that may be differently privileged within systems of power and systemic inequity (Burnes & Chen, 2012). Psychologists may also highlight and strengthen the development of TGNC people's competencies and resilience as they learn to manage the intersection of stigmatized identities (Singh, 2012).

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gender expression may affect the quality of care they provide to TGNC people and their families.

Rationale. Psychologists, like other members of society, come to their personal understanding and acceptance of different aspects of human diversity through a process of socialization. Psychologists' cultural biases, as well as the cultural differences between psychologists and their clients, have a clinical impact (Israel, Gorcheva, Burnes, & Walther, 2008; Vasquez, 2007). The assumptions, biases, and attitudes psychologists hold regarding TGNC people and gender identity and/or gender expression can affect the quality of services psychologists provide and their ability to develop an effective therapeutic alliance (Bess & Stabb, 2009; Rachlin, 2002). In addition, a lack of knowledge or training in providing affirmative care to TGNC people can limit a psychologist's effectiveness and perpetuate barriers to care (Bess & Stabb, 2009; Rachlin, 2002). Psychologists experienced with lesbian, gay, or bisexual (LGB) people may not be familiar with the unique needs of TGNC people (Israel, 2005; Israel et al., 2008). In community surveys, TGNC people have reported that many mental health care providers lack basic knowledge and skills relevant to care of TGNC people (Bradford, Xavier, Hendricks, Rives, & Honnold, 2007; Xavier, Bobbin, Singer, & Budd, 2005) and receive little training to prepare them to work with TGNC people (APA TFGIGV, 2009; Lurie, 2005). The National Transgender Discrimination Survey (Grant et al., 2011) reported that 50% of TGNC respondents shared that they had to educate their health care providers about TGNC care, 28% postponed seeking medical care due to antitrans bias, and 19% were refused care due to discrimination.

The APA ethics code (APA, 2010) specifies that psychologists practice in areas only within the boundaries of their competence (Standard 2.01), participate in proactive and consistent ways to enhance their competence (Standard 2.03), and base their work upon established scientific and professional knowledge (Standard 2.04). Competence in working with TGNC people can be developed through a range of activities, such as education, training, supervised experience, consultation, study, or professional experience.

Application. Psychologists may engage in practice with TGNC people in various ways; therefore, the depth and level of knowledge and competence required by a psychologist depends on the type and complexity of service offered to TGNC people. Services that psychologists provide to TGNC people require a basic understanding of the population and its needs, as well as the ability to respectfully interact in a trans-affirmative manner (L. Carroll, 2010).

APA emphasizes the use of evidence-based practice (APA Presidential Task Force on Evidence-Based Practice, 2006). Given how easily assumptions or stereotypes could influence treatment, evidence-based practice may be especially relevant to psychological practice with TGNC people. Until evidence-based practices are developed specifically for TGNC people, psychologists are encouraged to utilize existing evidence-based practices in the care they provide. APA also promotes collaboration with clients concerning clinical decisions, including issues related to costs, potential benefits, and the existing options and resources related to treatment (APA Presidential Task Force on Evidence-Based Practice, 2006). TGNC people could benefit from such collaboration and active engagement in decision

making, given the historical disenfranchisement and disempowerment of TGNC people in health care.

In an effort to develop competence in working with TGNC people, psychologists are encouraged to examine their personal beliefs regarding gender and sexuality, gender stereotypes, and TGNC identities, in addition to identifying gaps in their own knowledge, understanding, and acceptance (American Counseling Association [ACA], 2010). This examination may include exploring one's own gender identity and gendered experiences related to privilege, power, or marginalization, as well as seeking consultation and training with psychologists who have expertise in working with TGNC people and communities.

Psychologists are further encouraged to develop competence in working with TGNC people and their families by seeking up-to-date basic knowledge and understanding of gender identity and expression, and learning how to interact with TGNC people and their families respectfully and without judgment. Competence in working with TGNC people may be achieved and maintained in formal and informal ways, ranging from exposure in the curriculum of training programs for future psychologists and continuing education at professional conferences, to affirmative involvement as allies in the TGNC community. Beyond acquiring general competence, psychologists who choose to specialize in working with TGNC people presenting with gender-identity-related concerns are strongly encouraged to obtain advanced training, consultation, and professional experience (ACA, 2010; Coleman et al., 2012).

Psychologists may gain knowledge about the TGNC community and become more familiar with the complex social issues that affect the lives of TGNC people through first-hand experiences (e.g., attending community meetings and conferences, reading narratives written by TGNC people). If psychologists have not yet developed competence in working with TGNC people, it is recommended that they refer TGNC people to other psychologists or providers who are knowledgeable and able to provide trans-affirmative care.

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Rationale. Many TGNC people experience discrimination, ranging from subtle to severe, when accessing housing, health care, employment, education, public assistance, and other social services (Bazargan & Galvan, 2012; Bradford, Reisner, Honnold, & Xavier, 2013; Dispenza, Watson, Chung, & Brack, 2012; Grant et al., 2011). Discrimination can include assuming a person's assigned sex at birth is fully aligned with that person's gender identity, not using a person's preferred name or pronoun, asking TGNC people inappropriate questions about their bodies, or making the assumption that psychopathology exists given a specific gender identity or gender expression (Nadal, Rivera, & Corpus, 2010; Nadal, Skolnik, & Wong, 2012). Discrimination may also include refusing access to housing or employment or extreme acts of violence (e.g., sexual assault, murder). TGNC people who hold multiple marginalized identities are more vulnerable to discrimination and violence. TGNC women and people of color disproportionately experience severe forms of violence and discrimination, including police violence, and are less likely to receive help from law enforcement (Edelman, 2011; National Coalition of Anti-Violence Programs, 2011; Saffin, 2011).

TGNC people are at risk of experiencing antitrans prejudice and discrimination in educational settings. In a national representative sample of 7,898 LGBT youth in K-12 settings, 55.2% of participants reported verbal harassment, 22.7% reported physical harassment, and 11.4% reported physical assault based on their gender expression (Kosciw, Greytak, Palmer, & Boesen, 2014). In a national community survey of TGNC adults, 15% reported prematurely leaving educational settings ranging from kindergarten through college as a result of harassment (Grant et al., 2011). Many schools do not include gender identity and gender expression in their school nondiscrimination policies; this leaves TGNC youth without needed protections from bullying and aggression in schools (Singh & Jackson, 2012). TGNC youth in rural settings may be even more vulnerable to bullying and hostility in their school environments due to antitrans prejudice (Kosciw et al., 2014).

Inequities in educational settings and other forms of TGNC-related discrimination may contribute to the significant economic disparities TGNC people have reported. Grant and colleagues (2011) found that TGNC people were four times more likely to have a household income of less than $10,000 compared with cisgender people, and almost half of a sample of TGNC older adults reported a household income at or below 200% of poverty (Fredriksen-Goldsen et al., 2014). TGNC people often face workplace discrimination both when seeking and maintaining employment (Brewster, Velez, Mennicke, & Tebbe, 2014; Dispenza et al., 2012; Mizock & Mueser, 2014). In a nonrepresentative national study of TGNC people, 90% reported having "directly experienced harassment or mistreatment at work and felt forced to take protective actions that negatively impacted their careers or their well-being, such as hiding who they were to avoid workplace repercussions" (Grant et al., 2011, p. 56). In addition, 78% of respondents reported experiencing some kind of direct mistreatment or discrimination at work (Grant et al., 2011). Employment discrimination may be related to stigma based on a TGNC person's appearance, discrepancies in identity documentation, or being unable to provide job references linked to that person's pretransition name or gender presentation (Bender-Baird, 2011).

Issues of employment discrimination and workplace harassment are particularly salient for TGNC military personnel and veterans. Currently, TGNC people cannot serve openly in the U.S. military. Military regulations cite "transsexualism" as a medical exclusion from service (Department of Defense, 2011; Elders & Steinman, 2014). When

enlisted, TGNC military personnel are faced with very difficult decisions related to coming out, transition, and seeking appropriate medical and mental health care, which may significantly impact or end their military careers. Not surprisingly, research documents very high rates of suicidal ideation and behavior among TGNC military and veteran populations (Blosnich et al., 2013; Matarazzo et al., 2014). Being open about their TGNC identity with health care providers can carry risk for TGNC military personnel (OutServe-Servicemembers Legal Defense Network, n.d.). Barriers to accessing health care noted by TGNC veterans include viewing the VA health care system as an extension of the military, perceiving the VA as an unwelcoming environment, and fearing providers' negative reactions to their identity (Sherman, Kauth, Shipherd, & Street, 2014; Shipherd, Mizock, Maguen, & Green, 2012). A recent study shows 28% of LGBT veterans perceived their VA as welcoming and one third as unwelcoming (Sherman et al., 2014). Multiple initiatives are underway throughout the VA system to improve the quality and sensitivity of services to LGBT veterans.

Given widespread workplace discrimination and possible dismissal following transition, TGNC people may engage in sex work or survival sex (e.g., trading sex for food), or sell drugs to generate income (Grant et al., 2011; Hwahng & Nuttbrock, 2007; Operario, Soma, & Underhill, 2008; Stanley, 2011). This increases the potential for negative interactions with the legal system, such as harassment by the police, bribery, extortion, and arrest (Edelman, 2011; Testa et al., 2012), as well as increased likelihood of mental health symptoms and greater health risks, such as higher incidence of sexually transmitted infections, including HIV (Nemoto, Operario, Keatley, & Villegas, 2004).

Incarcerated TGNC people report harassment, isolation, forced sex, and physical assault, both by prison personnel and other inmates (American Civil Liberties Union National Prison Project, 2005; Brotheim, 2013; C. Daley, 2005). In sex-segregated facilities, TGNC people may be subjected to involuntary solitary confinement (also called "administrative segregation"), which can lead to severe negative mental and physical health consequences and may block access to services (Gallagher, 2014; National Center for Transgender Equality, 2012). Another area of concern is for TGNC immigrants and refugees. TGNC people in detention centers may not be granted access to necessary care and experience significant rates of assault and violence in these facilities (Gruberg, 2013). TGNC people may seek asylum in the United States to escape danger as a direct result of lack of protections in their country of origin (APA Presidential Task Force on Immigration, 2012; Cerezo, Morales, Quintero, & Rothman, 2014; Morales, 2013).

TGNC people have difficulty accessing necessary health care (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012) and often feel unsafe sharing their gender identity or their experiences of antitrans prejudice and discrimination due to historical and current discrimination from health care providers (Grant et al., 2011; Lurie, 2005; Singh & McKleroy, 2011). Even when TGNC people have health insurance, plans may explicitly exclude coverage related to gender transition (e.g., hormone therapy, surgery). TGNC people may also have difficulty accessing trans-affirmative primary health care if coverage for procedures is denied based on gender. For example, trans men may be excluded from necessary gynecological care based on the assumption that men do not need these services. These barriers often lead to a lack of preventive health care for TGNC people (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012). Although the landscape is beginning to change with the recent revision of Medicare policy (National Center for Transgender Equality, 2014) and changes to state laws (Transgender Law Center, n.d.), many TGNC people are still likely to have little to no access to TGNC-related health care as a result of the exclusions in their insurance.

Application. Awareness of and sensitivity to the effects of antitrans prejudice and discrimination can assist psychologists in assessing, treating, and advocating for their TGNC clients. When a TGNC person faces discrimination based on gender identity or gender expression, psychologists may facilitate emotional processing of these experiences and work with the person to identify supportive resources and possible courses of action. Specific needs of TGNC people might vary from developing self-advocacy strategies, to navigating public spaces, to seeking legal recourse for harassment and discrimination in social services and other systems. Additionally, TGNC people who have been traumatized by physical or emotional violence may need therapeutic support.

Psychologists may be able to assist TGNC people in accessing relevant social service systems. For example, psychologists may be able to assist in identifying health care providers and housing resources that are affirming and affordable, or locating affirming religious and spiritual communities (Glaser, 2008; Porter et al., 2013). Psychologists may also assist in furnishing documentation or official correspondence that affirms gender identity for the purpose of accessing appropriate public accommodations, such as bathroom use or housing (Lev, 2009; W. J. Meyer, 2009).

Additionally, psychologists may identify appropriate resources, information, and services to help TGNC people in addressing workplace discrimination, including strategies during a social and/or medical transition for identity disclosure at work. For those who are seeking employment, psychologists may help strategize about how and whether to share information about gender history. Psychologists may also work with employers to develop supportive policies for workplace gender transition or to develop training to help employees adjust to the transition of a coworker.

For TGNC military and veteran populations, psychologists may help to address the emotional impact of navigating TGNC identity development in the military system. Psychologists are encouraged to be aware that issues of confidentiality may be particularly sensitive with active duty or reserve status service members, as the consequences of being identified as TGNC may prevent the client's disclosure of gender identity in treatment.

In educational settings, psychologists may advocate for TGNC youth on a number of levels (APA & National

Association of School Psychologists, 2014; Boulder Valley School District, 2012). Psychologists may consult with administrators, teachers, and school counselors to provide resources and trainings on antitrans prejudice and developing safer school environments for TGNC students (Singh & Burnes, 2009). Peer support from other TGNC people has been shown to buffer the negative effect of stigma on mental health (Bockting et al., 2013). As such, psychologists may consider and develop peer-based interventions to facilitate greater understanding and respectful treatment of TGNC youth by cisgender peers (Case & Meier, 2014). Psychologists may work with TGNC youth and their families to identify relevant resources, such as school policies that protect gender identity and gender expression (APA & National Association of School Psychologists, 2014; Gonzalez & McNulty, 2010), referrals to TGNC-affirmative organizations, and online resources, which may be especially helpful for TGNC youth in rural settings.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Rationale. Antitrans prejudice and the adherence of mainstream society to the gender binary adversely affect TGNC people within their families, schools, health care, legal systems, workplaces, religious traditions, and communities (American Civil Liberties Union National Prison Project, 2005; Bradford et al., 2013; Brewster et al., 2014; Levy & Lo, 2013; McGuire, Anderson, & Toomey, 2010). TGNC people face challenges accessing gender-inclusive restrooms, which may result in discomfort when being forced to use a men's or women's restroom (Transgender Law Center, 2005). In addition to the emotional distress the forced binary choice that public restrooms may create for some, TGNC people are frequently concerned with others' reactions to their presence in public restrooms, including potential discrimination, harassment, and violence (Herman, 2013).

Many TGNC people may be distrustful of care providers due to previous experiences of being pathologized (Benson, 2013). Experiences of discrimination and prejudice with health care providers may be complicated by power differentials within the therapeutic relationship that may greatly affect or complicate the care that TGNC people experience. TGNC people have routinely been asked to obtain an endorsement letter from a psychologist attesting to the stability of their gender identity as a prerequisite to access an endocrinologist, surgeon, or legal institution (e.g., driver's license bureau; Lev, 2009). The need for such required documentation from a psychologist may influence rapport, resulting in TGNC people fearing prejudicial treatment in which this documentation is withheld or delayed by the treating provider (Bouman et al., 2014). Whether a TGNC person has personally experienced interactions with providers as disempowering or has learned from community members to expect such a dynamic, psychologists are encouraged to be prepared for TGNC people to be very cautious when entering into a therapeutic relationship. When TGNC people feel validated and empowered within the environment in which a psychologist practices, the therapeutic relationship will benefit and the person may be more willing to explore their authentic selves and share uncertainties and ambiguities that are a common part of TGNC identity development.

Application. Because many TGNC people experience antitrans prejudice or discrimination, psychologists are encouraged to ensure that their work settings are welcoming and respectful of TGNC people, and to be mindful of what TGNC people may perceive as unwelcoming. To do so, psychologists may educate themselves about the many ways that cisgender privilege and antitrans prejudice may be expressed. Psychologists may also have specific conversations with TGNC people about their experiences of the mental health system and implement feedback to foster TGNC-affirmative environments. As a result, when TGNC people access various treatment settings and public spaces, they may experience less harm, disempowerment, or pathologization, and thus will be more likely to avail themselves of resources and support.

Psychologists are encouraged to be proactive in considering how overt or subtle cues in their workplaces and other environments may affect the comfort and safety of TGNC people. To increase the comfort of TGNC people, psychologists are encouraged to display TGNC-affirmative resources in waiting areas and to avoid the display of items that reflect antitrans attitudes (Lev, 2009). Psychologists are encouraged to examine how their language (e.g., use of incorrect pronouns and names) may reinforce the gender binary in overt or subtle and unintentional ways (Smith, Shin, & Officer, 2012). It may be helpful for psychologists to provide training for support staff on how to respectfully interact with TGNC people. A psychologist may consider making changes to paperwork, forms, or outreach materials to ensure that these materials are more inclusive of TGNC people (Spade, 2011b). For example, demographic questionnaires can communicate respect through the use of inclusive language and the inclusion of a range of gender identities. In addition, psychologists may also work within their institutions to advocate for restrooms that are inclusive and accessible for people of all gender identities and/or gender expressions.

When working with TGNC people in a variety of care and institutional settings (e.g., inpatient medical and psychiatric hospitals, substance abuse treatment settings, nursing homes, foster care, religious communities, military and VA health care settings, and prisons), psychologists may become liaisons and advocates for TGNC people's mental health needs and for respectful treatment that addresses their gender identity in an affirming manner. In playing this role, psychologists may find guidance and best practices that have been published for particular institutional contexts to be helpful (e.g., Department of Veterans Affairs, Veterans' Health Administration, 2013; Glezer, McNiel, & Binder, 2013; Merksamer, 2011).

Guideline 7: Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

Rationale. The lack of public policy that addresses the needs of TGNC people creates significant hardships for them (Taylor, 2007). Although there have been major advances in legal protections for TGNC people in recent years (Buzuvis, 2013; Harvard Law Review Association, 2013), many TGNC people are still not afforded protections from discrimination on the basis of gender identity or expression (National LGBTQ Task Force, 2013; Taylor, 2007). For instance, in many states, TGNC people do not have employment or housing protections and may be fired or lose their housing based on their gender identity. Many policies that protect the rights of cisgender people, including LGB people, do not protect the rights of TGNC people (Currah, & Minter, 2000; Spade, 2011a).

TGNC people can experience challenges obtaining gender-affirming identity documentation (e.g., birth certificate, passport, social security card, driver's license). For TGNC people experiencing poverty or economic hardship, requirements for obtaining this documentation may be impossible to meet, in part due to the difficulty of securing employment without identity documentation that aligns with their gender identity and gender expression (Sheridan, 2009). Additionally, systemic barriers related to binary gender identification systems prevent some TGNC people from changing their documents, including those who are incarcerated, undocumented immigrants, and people who live in jurisdictions that explicitly forbid such changes (Spade, 2006). Documentation requirements can also assume a universal TGNC experience that marginalizes some TGNC people, especially those who do not undergo a medical transition. This may affect a TGNC person's social and psychological well-being and interfere with accessing employment, education, housing and shelter, health care, public benefits, and basic life management resources (e.g., opening a bank account).

Application. Psychologists are encouraged to inform public policy to reduce negative systemic impact on TGNC people and to promote positive social change. Psychologists are encouraged to identify and improve systems that permit violence; educational, employment, and housing discrimination; lack of access to health care; unequal access to other vital resources; and other instances of systemic inequity that TGNC people experience (ACA, 2010). Many TGNC people experience stressors from constant barriers, inequitable treatment, and forced release of sensitive and private information about their bodies and their lives (Hendricks & Testa, 2012). To obtain proper identity documentation, TGNC people may be required to provide court orders, proof of having had surgery, and documentation of psychotherapy or a psychiatric diagnosis. Psychologists may assist TGNC people by normalizing their reactions of fatigue and traumatization while interacting with legal systems and requirements; TGNC people may also benefit from guidance about alternate avenues of recourse, self-advocacy, or appeal. When TGNC people feel that it is unsafe to advocate for themselves, psychologists may work with their clients to access appropriate resources in the community.

Psychologists are encouraged to be sensitive to the challenges of attaining gender-affirming identity documentation and how the receipt or denial of such documentation may affect social and psychological well-being, the person's ability to obtain education and employment, find safe housing, access public benefits, obtain student loans, and access health insurance. It may be of significant assistance for psychologists to understand and offer information about the process of a legal name change, gender marker change on identification, or the process for accessing other gender-affirming documents. Psychologists may consult the National Center for Transgender Equality, the Sylvia Rivera Law Project, or the Transgender Law Center for additional information on identity documentation for TGNC people.

Psychologists may choose to become involved with an organization that seeks to revise law and public policy to better protect the rights and dignities of TGNC people. Psychologists may participate at the local, state, or national level to support TGNC-affirmative health care accessibility, human rights in sex-segregated facilities, or policy change regarding gender-affirming identity documentation. Psychologists working in institutional settings may also expand their roles to work as collaborative advocates for TGNC people (Gonzalez & McNulty, 2010). Psychologists are encouraged to provide written affirmations supporting TGNC people and their gender identity so that they may access necessary services (e.g., hormone therapy).

Life Span Development

Guideline 8. Psychologists working with gender-questioning [4] and TGNC youth understand the different developmental needs of children and adolescents, and that not all youth will persist in a TGNC identity into adulthood.

Rationale. Many children develop stability (constancy across time) in their gender identity between Ages 3 to 4 (Kohlberg, 1966), although gender consistency (recognition that gender remains the same across situations) often does not occur until Ages 4 to 7 (Siegal & Robinson, 1987). Children who demonstrate gender nonconformity in preschool and early elementary years may not follow this trajectory (Zucker & Bradley, 1995). Existing research suggests that between 12% and 50% of children diagnosed with gender dysphoria may persist in their identification with a gender different than sex assigned at birth into late adolescence and young adulthood (Drummond, Bradley,

[4] Gender-questioning youth are differentiated from TGNC youth in this section of the guidelines. Gender-questioning youth may be questioning or exploring their gender identity but have not yet developed a TGNC identity. As such, they may not be eligible for some services that would be offered to TGNC youth. Gender-questioning youth are included here because gender questioning may lead to a TGNC identity.

Peterson-Badaali, & Zucker, 2008; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013; Wallien & Cohen-Kettenis, 2008). However, several research studies categorized 30% to 62% of youth who did not return to the clinic for medical intervention after initial assessment, and whose gender identity may be unknown, as "desisters" who no longer identified with a gender different than sex assigned at birth (Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008a). As a result, this research runs a strong risk of inflating estimates of the number of youth who do not persist with a TGNC identity. Research has suggested that children who identify more intensely with a gender different than sex assigned at birth are more likely to persist in this gender identification into adolescence (Steensma et al., 2013), and that when gender dysphoria persists through childhood and intensifies into adolescence, the likelihood of long-term TGNC identification increases (A. L. de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2011; Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008b). Gender-questioning children who do not persist may be more likely to later identify as gay or lesbian than non-gender-questioning children (Bailey & Zucker, 1995; Drescher, 2014; Wallien & Cohen-Kettenis, 2008).

A clear distinction between care of TGNC and gender-questioning children and adolescents exists in the literature. Due to the evidence that not all children persist in a TGNC identity into adolescence or adulthood, and because no approach to working with TGNC children has been adequately, empirically validated, consensus does not exist regarding best practice with prepubertal children. Lack of consensus about the preferred approach to treatment may be due in part to divergent ideas regarding what constitutes optimal treatment outcomes for TGNC and gender-questioning youth (Hembree et al., 2009). Two distinct approaches exist to address gender identity concerns in children (Hill, Menvielle, Sica, & Johnson, 2010; Wallace & Russell, 2013), with some authors subdividing one of the approaches to suggest three (Byne et al., 2012; Drescher, 2014; Stein, 2012).

One approach encourages an affirmation and acceptance of children's expressed gender identity. This may include assisting children to socially transition and to begin medical transition when their bodies have physically developed, or allowing a child's gender identity to unfold without expectation of a specific outcome (A. L. de Vries & Cohen-Kettenis, 2012; Edwards-Leeper & Spack, 2012; Ehrensaft, 2012; Hidalgo et al., 2013; Tishelman et al., 2015). Clinicians using this approach believe that an open exploration and affirmation will assist children to develop coping strategies and emotional tools to integrate a positive TGNC identity should gender questioning persist (Edwards-Leeper & Spack, 2012).

In the second approach, children are encouraged to embrace their given bodies and to align with their assigned gender roles. This includes endorsing and supporting behaviors and attitudes that align with the child's sex assigned at birth prior to the onset of puberty (Zucker, 2008a; Zucker, Wood, Singh, & Bradley, 2012). Clinicians using this approach believe that undergoing multiple medical interventions and living as a TGNC person in a world that stigmatizes gender nonconformity is a less desirable outcome than one in which children may be assisted to happily align with their sex assigned at birth (Zucker et al., 2012). Consensus does not exist regarding whether this approach may provide benefit (Zucker, 2008a; Zucker et al., 2012) or may cause harm or lead to psychosocial adversities (Hill et al., 2010; Pyne, 2014; Travers et al., 2012; Wallace & Russell, 2013). When addressing psychological interventions for children and adolescents, the World Professional Association for Transgender Health Standards of Care identify interventions "aimed at trying to change gender identity and expression to become more congruent with sex assigned at birth" as unethical (Coleman et al., 2012, p. 175). It is hoped that future research will offer improved guidance in this area of practice (Adelson & AACAP CQI, 2012; Malpas, 2011).

Much greater consensus exists regarding practice with adolescents. Adolescents presenting with gender identity concerns bring their own set of unique challenges. This may include having a late-onset (i.e., postpubertal) presentation of gender nonconforming identification, with no history of gender role nonconformity or gender questioning in childhood (Edwards-Leeper & Spack, 2012). Complicating their clinical presentation, many gender-questioning adolescents also present with co-occurring psychological concerns, such as suicidal ideation, self-injurious behaviors (Liu & Mustanski, 2012; Mustanski, Garofalo, & Emerson, 2010), drug and alcohol use (Garofalo et al., 2006), and autism spectrum disorders (A. L. de Vries, Noens, Cohen-Kettenis, van Berckelaer-Onnes, & Doreleijers, 2010; Jones et al., 2012). Additionally, adolescents can become intensely focused on their immediate desires, resulting in outward displays of frustration and resentment when faced with any delay in receiving the medical treatment from which they feel they would benefit and to which they feel entitled (Angello, 2013; Edwards-Leeper & Spack, 2012). This intense focus on immediate needs may create challenges in assuring that adolescents are cognitively and emotionally able to make life-altering decisions to change their name or gender marker, begin hormone therapy (which may affect fertility), or pursue surgery.

Nonetheless, there is greater consensus that treatment approaches for adolescents affirm an adolescents' gender identity (Coleman et al., 2012). Treatment options for adolescents extend beyond social approaches to include medical approaches. One particular medical intervention involves the use of puberty-suppressing medication or "blockers" (GnRH analogue), which is a reversible medical intervention used to delay puberty for appropriately screened adolescents with gender dysphoria (Coleman et al., 2012; A. L. C. de Vries et al., 2014; Edwards-Leeper, & Spack, 2012). Because of their age, other medical interventions may also become available to adolescents, and psychologists are frequently consulted to provide an assessment of whether such procedures would be advisable (Coleman et al., 2012).

Application. Psychologists working with TGNC and gender-questioning youth are encouraged to regularly review the most current literature in this area, recognizing the limited available research regarding the potential benefits and risks of different treatment approaches for children and for adolescents. Psychologists are encouraged to offer parents and guardians clear information about available treatment approaches, regardless of the specific approach chosen by the psychologist. Psychologists are encouraged to provide psychological service to TGNC and gender-questioning children and adolescents that draws from empirically validated literature when available, recognizing the influence psychologists' values and beliefs may have on the treatment approaches they select (Ehrbar & Gorton, 2010). Psychologists are also encouraged to remain aware that what one youth and/or parent may be seeking in a therapeutic relationship may not coincide with a clinician's approach (Brill & Pepper, 2008). In cases in which a youth and/or parent identify different preferred treatment outcomes than a clinician, it may not be clinically appropriate for the clinician to continue working with the youth and family, and alternative options, including referral, might be considered. Psychologists may also find themselves navigating family systems in which youth and their caregivers are seeking different treatment outcomes (Edwards-Leeper & Spack, 2012). Psychologists are encouraged to carefully reflect on their personal values and beliefs about gender identity development in conjunction with the available research, and to keep the best interest of the child or adolescent at the forefront of their clinical decisions at all times.

Because gender nonconformity may be transient for younger children in particular, the psychologist's role may be to help support children and their families through the process of exploration and self-identification (Ehrensaft, 2012). Additionally, psychologists may provide parents with information about possible long-term trajectories children may take in regard to their gender identity, along with the available medical interventions for adolescents whose TGNC identification persists (Edwards-Leeper & Spack, 2012).

When working with adolescents, psychologists are encouraged to recognize that some TGNC adolescents will not have a strong history of childhood gender role nonconformity or gender dysphoria either by self-report or family observation (Edwards-Leeper & Spack, 2012). Some of these adolescents may have withheld their feelings of gender nonconformity out of a fear of rejection, confusion, conflating gender identity and sexual orientation, or a lack of awareness of the option to identify as TGNC. Parents of these adolescents may need additional assistance in understanding and supporting their youth, given that late-onset gender dysphoria and TGNC identification may come as a significant surprise. Moving more slowly and cautiously in these cases is often advisable (Edwards-Leeper & Spack, 2012). Given the possibility of adolescents' intense focus on immediate desires and strong reactions to perceived delays or barriers, psychologists are encouraged to validate these concerns and the desire to move through the process quickly while also remaining thoughtful and deliberate in treatment. Adolescents and their families may need support in tolerating ambiguity and uncertainty with regard to gender identity and its development (Brill & Pepper, 2008). It is encouraged that care should be taken not to foreclose this process.

For adolescents who exhibit a long history of gender nonconformity, psychologists may inform parents that the adolescent's self-affirmed gender identity is most likely stable (A. L. de Vries et al., 2011). The clinical needs of these adolescents may be different than those who are in the initial phases of exploring or questioning their gender identity. Psychologists are encouraged to complete a comprehensive evaluation and ensure the adolescent's and family's readiness to progress while also avoiding unnecessary delay for those who are ready to move forward.

Psychologists working with TGNC and gender-questioning youth are encouraged to become familiar with medical treatment options for adolescents (e.g., puberty-suppressing medication, hormone therapy) and work collaboratively with medical providers to provide appropriate care to clients. Because the ongoing involvement of a knowledgeable mental health provider is encouraged due to the psychosocial implications, and is often also a required part of the medical treatment regimen that may be offered to TGNC adolescents (Coleman et al., 2012; Hembree et al., 2009), psychologists often play an essential role in assisting in this process.

Psychologists may encourage parents and caregivers to involve youth in developmentally appropriate decision making about their education, health care, and peer networks, as these relate to children's and adolescents' gender identity and gender expression (Ryan, Russell, Huebner, Diaz, & Sanchez, 2010). Psychologists are also encouraged to educate themselves about the advantages and disadvantages of social transition during childhood and adolescence, and to discuss these factors with both their young clients and clients' parents. Emphasizing to parents the importance of allowing their child the freedom to return to a gender identity that aligns with sex assigned at birth or another gender identity at any point cannot be overstated, particularly given the research that suggests that not all young gender nonconforming children will ultimately express a gender identity different from that assigned at birth (Wallien, & Cohen-Kettenis, 2008; Zucker & Bradley, 1995). Psychologists are encouraged to acknowledge and explore the fear and burden of responsibility that parents and caregivers may feel as they make decisions about the health of their child or adolescent (Grossman, D'Augelli, Howell, & Hubbard, 2006). Parents and caregivers may benefit from a supportive environment to discuss feelings of isolation, explore loss and grief they may experience, vent anger and frustration at systems that disrespect or discriminate against them and their youth, and learn how to communicate with others about their child's or adolescent's gender identity or gender expression (Brill & Pepper, 2008).

Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Rationale. Little research has been conducted about TGNC elders, leaving much to be discovered about this life stage for TGNC people (Auldridge, Tamar-Mattis, Kennedy, Ames, & Tobin, 2012). Socialization into gender role behaviors and expectations based on sex assigned at birth, as well as the extent to which TGNC people adhere to these societal standards, is influenced by the chronological age at which a person self-identifies as TGNC, the age at which a person comes out or socially and/or medically transitions (Birren & Schaie, 2006; Bockting & Coleman, 2007; Cavanaugh & Blanchard-Fields, 2010; Nuttbrock et al., 2010; Wahl, Iwarsson, & Oswald, 2012), and a person's generational cohort (e.g., 1950 vs. 2010; Fredriksen-Goldsen et al., 2011).

Even decades after a medical or social transition, TGNC elders may still subscribe to the predominant gender role expectations that existed at the time of their transition (Knochel, Croghan, Moore, & Quam, 2011). Prior to the 1980s, TGNC people who transitioned were strongly encouraged by providers to pass in society as cisgender and heterosexual and to avoid associating with other TGNC people (Benjamin, 1966; R. Green & Money, 1969; Hastings, 1974; Hastings & Markland, 1978). Even TGNC elders who were comfortable telling others about their TGNC identity when they were younger may choose not to reveal their identity at a later stage of life (Ekins & King, 2005; Ippolito & Witten, 2014). Elders' unwillingness to disclose their TGNC identity can result from feelings of physical vulnerability or increased reliance on others who may discriminate against them or treat them poorly as a result of their gender identity (Bockting & Coleman, 2007), especially if the elder resides in an institutionalized setting (i.e., nursing home, assisted living facility) and relies on others for many daily needs (Auldridge et al., 2012). TGNC elders are also at a heightened risk for depression, suicidal ideation, and loneliness compared with LGB elders (Auldridge et al., 2012; Fredriksen-Goldsen et al., 2011).

A Transgender Law Center survey found that TGNC and LGB elders had less financial well-being than their younger cohorts, despite having a higher than average educational level for their age group compared with the general population (Hartzell, Frazer, Wertz, & Davis, 2009). Survey research has also revealed that TGNC elders experience underemployment and gaps in employment, often due to discrimination (Auldridge et al., 2012; Beemyn & Rankin, 2011; Factor & Rothblum, 2007). In the past, some TGNC people with established careers may have been encouraged by service providers to find new careers or jobs to avoid undergoing a gender transition at work or being identified as TGNC, potentially leading to a significant loss of income and occupational identity (Cook-Daniels, 2006). Obstacles to employment can increase economic disparities that result in increased needs for supportive housing and other social services (National Center for Transgender Equality, 2012; Services and Advocacy for GLBT Elders & National Center for Transgender Equality, 2012).

TGNC elders may face obstacles to seeking or accessing resources that support their physical, financial, or emotional well-being. For instance, they may be concerned about applying for social security benefits, fearing that their TGNC identity may become known (Hartzell et al., 2009). A TGNC elder may avoid medical care, increasing the likelihood of later needing a higher level of medical care (e.g., home-based care, assisted living, or nursing home) than their same-age cisgender peers (Hartzell et al., 2009; Ippolito & Witten, 2014; Mikalson et al., 2012). Nursing homes and assisted living facilities are rarely sensitive to the unique medical needs of TGNC elders (National Senior Citizens Law Center, 2011). Some TGNC individuals who enter congregate housing, assisted living, or long-term care settings may feel the need to reverse their transition to align with sex assigned at birth to avoid discrimination and persecution by other residents and staff (Ippolito & Witten, 2014).

Older age may both facilitate and complicate medical treatment related to gender transition. TGNC people who begin hormone therapy later in life may have a smoother transition due to waning hormone levels that are a natural part of aging (Witten & Eyler, 2012). Age may also influence the decisions TGNC elders make regarding sex-affirmation surgeries, especially if physical conditions exist that could significantly increase risks associated with surgery or recovery.

Much has been written about the resilience of elders who have endured trauma (Fuhrmann & Shevlowitz, 2006; Hardy, Concato, & Gill, 2004; Mlinac, Sheeran, Blissmer, Lees, & Martins, 2011; Rodin & Stewart, 2012). Although some TGNC elders have experienced significant psychological trauma related to their gender identity, some also have developed resilience and effective ways of coping with adversity (Fruhauf & Orel, 2015). Despite the limited availability of LGBTQ-affirmative religious organizations in many local communities, TGNC elders make greater use of these resources than their cisgender peers (Porter et al., 2013).

Application. Psychologists are encouraged to seek information about the biopsychosocial needs of TGNC elders to inform case conceptualization and treatment planning to address psychological, social, and medical concerns. Many TGNC elders are socially isolated. Isolation can occur as a result of a loss of social networks through death or through disclosure of a TGNC identity. Psychologists may assist TGNC elders in establishing new social networks that support and value their TGNC identity, while also working to strengthen existing family and friend networks after a TGNC identity has been disclosed. TGNC elders may find special value in relationships with others in their generational cohort or those who may have similar coming-out experiences. Psychologists may encourage TGNC elders to identify ways they can mentor and improve the resilience of younger TGNC generations, creating a sense of generativity (Erikson, 1968) and contribu-

tion while building new supportive relationships. Psychologists working with TGNC elders may help them recognize the sources of their resilience and encourage them to connect with and be active in their communities (Fuhrmann & Craffey, 2014).

For TGNC elders who have chosen not to disclose their gender identity, psychologists may provide support to address shame, guilt, or internalized antitrans prejudice, and validate each person's freedom to choose their pattern of disclosure. Clinicians may also provide validation and empathy when TGNC elders have chosen a model of transition that avoids any disclosure of gender identity and is heavily focused on passing as cisgender.

TGNC elders who choose to undergo a medical or social transition in older adulthood may experience antitrans prejudice from people who question the value of transition at an older age or who believe that these elders are not truly invested in their transition or in a TGNC identity given the length of time they have waited (Auldridge et al., 2012). Some TGNC elders may also grieve lost time and missed opportunities. Psychologists may validate elders' choices to come out, transition, or evolve their gender identity or gender expression at any age, recognizing that such choices may have been much less accessible or viable at earlier stages of TGNC elders' lives.

Psychologists may assist congregate housing, assisted living, or long-term care settings to best meet TGNC elders' needs through respectful communication and affirmation of each person's gender identity and gender expression. Psychologists may work with TGNC people in hospice care systems to develop an end-of-life plan that respects the person's wishes about disclosure of gender identity during and after death.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Rationale. TGNC people may seek assistance from psychologists in addressing gender-related concerns, other mental health issues, or both. Mental health problems experienced by a TGNC person may or may not be related to that person's gender identity and/or may complicate assessment and intervention of gender-related concerns. In some cases, there may not be a relationship between a person's gender identity and a co-occurring condition (e.g., depression, PTSD, substance abuse). In other cases, having a TGNC identity may lead or contribute to a co-occurring mental health condition, either directly by way of gender dysphoria, or indirectly by way of minority stress and oppression (Hendricks & Testa, 2012; I. H. Meyer, 1995, 2003). In extremely rare cases, a co-occurring condition can mimic gender dysphoria (i.e., a psychotic process that distorts the perception of one's gender; Baltieri & De Andrade, 2009; Hepp, Kraemer, Schnyder, Miller, & Delsignore, 2004).

Regardless of the presence or absence of an etiological link, gender identity may affect how a TGNC person experiences a co-occurring mental health condition, and/or a co-occurring mental health condition may complicate the person's gender expression or gender identity. For example, an eating disorder may be influenced by a TGNC person's gender expression (e.g., rigid eating patterns used to manage body shape or menstruation may be related to gender identity or gender dysphoria; Ålgars, Alanko, Santtila, & Sandnabba, 2012; Murray, Boon, & Touyz, 2013). In addition, the presence of autism spectrum disorder may complicate a TGNC person's articulation and exploration of gender identity (Jones et al., 2012). In cases in which gender dysphoria is contributing to other mental health concerns, treatment of gender dysphoria may be helpful in alleviating those concerns as well (Keo-Meier et al., 2015).

A relationship also exists between mental health conditions and the psychological sequelae of minority stress that TGNC people can experience. Given that TGNC people experience physical and sexual violence (Clements-Nolle et al., 2006; Kenagy & Bostwick, 2005; Lombardi, Wilchins, Priesing, & Malouf, 2001; Xavier et al., 2005), general harassment and discrimination (Beemyn & Rankin, 2011; Factor & Rothblum, 2007), and employment and housing discrimination (Bradford et al., 2007), they are likely to experience significant levels of minority stress. Studies have demonstrated the disproportionately high levels of negative psychological sequelae related to minority stress, including suicidal ideation and suicide attempts (Center for Substance Abuse Treatment, 2012; Clements-Nolle et al., 2006; Cochran & Cauce, 2006; Nuttbrock et al., 2010; Xavier et al., 2005) and completed suicides (Dhejne et al., 2011; van Kesteren, Asscheman, Megens, & Gooren, 1997). Recent studies have begun to demonstrate an association between sources of external stress and psychological distress (Bockting et al., 2013; Nuttbrock et al., 2010), including suicidal ideation and attempts and self-injurious behavior (dickey, Reisner, & Juntunen, 2015; Goldblum et al., 2012; Testa et al., 2012).

The minority stress model accounts for both the negative mental health effects of stigma-related stress and the processes by which members of the minority group may develop resilience and resistance to the negative effects of stress (I. H. Meyer, 1995, 2003). Although the minority stress model was developed as a theory of the relationship between sexual orientation and mental disorders, the model has been adapted to TGNC populations (Hendricks & Testa, 2012).

Application. Because of the increased risk of stress-related mental health conditions, psychologists are encouraged to conduct a careful diagnostic assessment, including a differential diagnosis, when working with TGNC people (Coleman et al., 2012). Taking into account the intricate interplay between the effects of mental health symptoms and gender identity and gender expression, psychologists are encouraged to neither ignore mental health problems a TGNC person is experiencing, nor erroneously

assume that those mental health problems are a result of the person's gender identity or gender expression. Psychologists are strongly encouraged to be cautious before determining that gender nonconformity or dysphoria is due to an underlying psychotic process, as this type of causal relationship is rare.

When TGNC people seek to access transition-related health care, a psychosocial assessment is often part of this process (Coleman et al., 2012). A comprehensive and balanced assessment typically includes not only information about a person's past experiences of antitrans prejudice or discrimination, internalized messages related to these experiences, and anticipation of future victimization or rejection (Coolhart, Provancher, Hager, & Wang, 2008), but also coping strategies and sources of resilience (Hendricks & Testa, 2012; Singh et al., 2011). Gathering information about negative life events directly related to a TGNC person's gender identity and gender expression may assist psychologists in understanding the sequelae of stress and discrimination, distinguishing them from concurrent and potentially unrelated mental health problems. Similarly, when a TGNC person has a primary presenting concern that is not gender focused, a comprehensive assessment takes into account that person's experience relative to gender identity and gender expression, including any discrimination, just as it would include assessing other potential trauma history, medical concerns, previous experience with helping professionals, important future goals, and important aspects of identity. Strategies a TGNC person uses to navigate antitrans discrimination could be sources of strength to deal with life challenges or sources of distress that increase challenges and barriers.

Psychologists are encouraged to help TGNC people understand the pervasive influence of minority stress and discrimination that may exist in their lives, potentially including internalized negative attitudes about themselves and their TGNC identity (Hendricks & Testa, 2012). With this support, clients can better understand the origins of their mental health symptoms and normalize their reactions when faced with TGNC-related inequities and discrimination. Minority stress models also identify potentially important sources of resilience. TGNC people can develop resilience when they connect with other TGNC people who provide information on how to navigate antitrans prejudice and increase access to necessary care and resources (Singh et al., 2011). TGNC people may need help developing social support systems to nurture their resilience and bolster their ability to cope with the adverse effects of antitrans prejudice and/or discrimination (Singh & McKleroy, 2011).

Feminizing or masculinizing hormone therapy can positively or negatively affect existing mood disorders (Coleman et al., 2012). Psychologists may also help TGNC people who are in the initial stages of hormone therapy adjust to normal changes in how they experience emotions. For example, trans women who begin estrogens and antiandrogens may experience a broader range of emotions than they are accustomed to, or trans men beginning testosterone might be faced with adjusting to a higher libido and feeling more emotionally reactive in stressful situations. These changes can be normalized as similar to the emotional adjustments that cisgender women and men experience during puberty. Some TGNC people will be able to adapt existing coping strategies, whereas others may need help developing additional skills (e.g., emotional regulation or assertiveness). Readers are encouraged to refer to the World Professional Association for Transgender Health Standards of Care for discussion of the possible effects of hormone therapy on a TGNC person's mood, affect, and behavior (Coleman et al., 2012).

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Rationale. Research has primarily shown positive treatment outcomes when TGNC adults and adolescents receive TGNC-affirmative medical and psychological services (i.e., psychotherapy, hormones, surgery; Byne et al., 2012; R. Carroll, 1999; Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008; Davis & Meier, 2014; De Cuypere et al., 2006; Gooren, Giltay, & Bunck, 2008; Kuhn et al., 2009), although sample sizes are frequently small with no population-based studies. In a meta-analysis of the hormone therapy treatment literature with TGNC adults and adolescents, researchers reported that 80% of participants receiving trans-affirmative care experienced an improved quality of life, decreased gender dysphoria, and a reduction in negative psychological symptoms (Murad et al., 2010).

In addition, TGNC people who receive social support about their gender identity and gender expression have improved outcomes and quality of life (Brill & Pepper, 2008; Pinto, Melendez, & Spector, 2008). Several studies indicate that family acceptance of TGNC adolescents and adults is associated with decreased rates of negative outcomes, such as depression, suicide, and HIV risk behaviors and infection (Bockting et al., 2013; Dhejne et al., 2011; Grant et al., 2011; Liu & Mustanski, 2012; Ryan, 2009). Family support is also a strong protective factor for TGNC adults and adolescents (Bockting et al., 2013; Moody & Smith, 2013; Ryan et al., 2010). TGNC people, however, frequently experience blatant or subtle antitrans prejudice, discrimination, and even violence within their families (Bradford et al., 2007). Such family rejection is associated with higher rates of HIV infection, suicide, incarceration, and homelessness for TGNC adults and adolescents (Grant et al., 2011; Liu & Mustanski, 2012). Family rejection and lower levels of social support are significantly correlated with depression (Clements-Nolle et al., 2006; Ryan, 2009). Many TGNC people seek support through peer relationships, chosen families, and communities in which they may be more likely to experience acceptance (Gonzalez & McNulty, 2010; Nuttbrock et al., 2009). Peer support from other TGNC people has been found to be a moderator between antitrans discrimination and mental health, with higher levels of peer support associated with better mental health (Bockting et al., 2013). For some TGNC people, support from religious and spiritual communities provides

an important source of resilience (Glaser, 2008; Kidd & Witten, 2008; Porter et al., 2013).

Application. Given the strong evidence for the positive influence of affirmative care, psychologists are encouraged to facilitate access to and provide trans-affirmative care to TGNC people. Whether through the provision of assessment and psychotherapy, or through assisting clients to access hormone therapy or surgery, psychologists may play a critical role in empowering and validating TGNC adults' and adolescents' experiences and increasing TGNC people's positive life outcomes (Bess & Stabb, 2009; Rachlin, 2002).

Psychologists are also encouraged to be aware of the importance of affirmative social support and assist TGNC adults and adolescents in building social support networks in which their gender identity is accepted and affirmed. Psychologists may assist TGNC people in negotiating family dynamics that may arise in the course of exploring and establishing gender identity. Depending on the context of psychological practice, these issues might be addressed in individual work with TGNC clients, conjoint sessions including members of their support system, family therapy, or group therapy. Psychologists may help TGNC people decide how and when to reveal their gender identity at work or school, in religious communities, and to friends and contacts in other settings. TGNC people who decide not to come out in all aspects of their lives can still benefit from TGNC-affirmative in-person or online peer support groups.

Clients may ask psychologists to assist family members in exploring feelings about their loved one's gender identity and gender expression. Published models of family adjustment (Emerson & Rosenfeld, 1996) may be useful to help normalize family members' reactions upon learning that they have a TGNC family member, and to reduce feelings of isolation. When working with family members or significant others, it may be helpful to normalize feelings of loss or fear of what may happen to current relationships as TGNC people disclose their gender identity and expression to others. Psychologists may help significant others adjust to changing relationships and consider how to talk to extended family, friends, and other community members about TGNC loved ones. Providing significant others with referrals to TGNC-affirmative providers, educational resources, and support groups can have a profound impact on their understanding of gender identity and their communication with TGNC loved ones. Psychologists working with couples and families may also help TGNC people identify ways to include significant others in their social or medical transition.

Psychologists working with TGNC people in rural settings may provide clients with resources to connect with other TGNC people online or provide information about in-person support groups in which they can explore the unique challenges of being TGNC in these geographic areas (Walinsky & Whitcomb, 2010). Psychologists serving TGNC military and veteran populations are encouraged to be sensitive to the barriers these individuals face, especially for people who are on active duty in the U.S. military (OutServe-Servicemembers Legal Defense Network, n.d.). Psychologists may help TGNC military members and veterans establish specific systems of support that create a safe and affirming space to reduce isolation and to create a network of peers with a shared military experience. Psychologists who work with veterans are encouraged to educate themselves on recent changes to VA policy that support equal access to VA medical and mental health services (Department of Veterans Affairs, Veterans' Health Administration, 2013).

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Rationale. Relationships involving TGNC people can be healthy and successful (Kins, Hoebeke, Heylens, Rubens, & De Cuyprere, 2008; Meier, Sharp, Michonski, Babcock, & Fitzgerald, 2013) as well as challenging (Brown, 2007; Iantaffi & Bockting, 2011). A study of successful relationships between TGNC men and cisgender women found that these couples attributed the success of their relationship to respect, honesty, trust, love, understanding, and open communication (Kins et al., 2008). Just as relationships between cisgender people can involve abuse, so can relationships between TGNC people and their partners (Brown, 2007), with some violent partners threatening to disclose a TGNC person's identity to exact control in the relationship (FORGE, n.d.).

In the early decades of medical and social transition for TGNC people, only those whose sexual orientations would be heterosexual posttransition (e.g., trans woman with a cisgender man) were deemed eligible for medical and social transition (Meyerowitz, 2002). This restriction prescribed only certain relationship partners (American Psychiatric Association, 1980; Benjamin, 1966; Chivers & Bailey, 2000), denied access to surgery for trans men identifying as gay or bisexual (Coleman & Bockting, 1988), or trans women identifying as lesbian or bisexual, and even required that TGNC people's existing legal marriages be dissolved before they could gain access to transition care (Lev, 2004).

Disclosure of a TGNC identity can have an important impact on the relationship between TGNC people and their partners. Disclosure of TGNC status earlier in the relationship tends to be associated with better relationship outcomes, whereas disclosure of TGNC status many years into an existing relationship may be perceived as a betrayal (Erhardt, 2007). When a TGNC person comes out in the context of an existing relationship, it can also be helpful if both partners are involved in decision making about the use of shared resources (i.e., how to balance the financial costs of transition with other family needs) and how to share this news with shared supports (i.e., friends and family). Sometimes relationship roles are renegotiated in the context of a TGNC person coming out to their partner (Samons, 2008). Assumptions about what it means to be a "husband" or a "wife" can shift if the gender identity of one's spouse shifts

(Erhardt, 2007). Depending on when gender issues are disclosed and how much of a change this creates in the relationship, partners may grieve the loss of aspects of their partner and the way the relationship used to be (Lev, 2004).

Although increasing alignment between gender identity and gender expression, whether it be through dress, behavior, or through medical interventions (i.e., hormones, surgery), does not necessarily affect to whom a TGNC person is attracted (Coleman et al., 1993), TGNC people may become more open to exploring their sexual orientation, may redefine sexual orientation as they move through transition, or both (Daskalos, 1998; H. Devor, 1993; Schleifer, 2006). Through increased comfort with their body and gender identity, TGNC people may explore aspects of their sexual orientation that were previously hidden or that felt discordant with their sex assigned at birth. Following a medical and/or social transition, a TGNC person's sexual orientation may remain constant or shift, either temporarily or permanently (e.g., renewed exploration of sexual orientation in the context of TGNC identity, shift in attraction or choice of sexual partners, widened spectrum of attraction, shift in sexual orientation identity; Meier, Sharp et al., 2013; Samons, 2008). For example, a trans man previously identified as a lesbian may later be attracted to men (Coleman et al., 1993; dickey, Burnes, & Singh, 2012), and a trans woman attracted to women pretransition may remain attracted to women posttransition (Lev, 2004).

Some TGNC people and their partners may fear the loss of mutual sexual attraction and other potential effects of shifting gender identities in the relationship. Lesbian-identified partners of trans men may struggle with the idea that being in a relationship with a man may cause others to perceive them as a heterosexual couple (Califia, 1997). Similarly, women in heterosexual relationships who later learn that their partners are trans women may be unfamiliar with navigating stigma associated with sexual minority status when viewed as a lesbian couple (Erhardt, 2007). Additionally, partners may find they are not attracted to a partner after transition. As an example, a lesbian whose partner transitions to a male identity may find that she is no longer attracted to this person because she is not sexually attracted to men. Partners of TGNC people may also experience grief and loss as their partners engage in social and/or medical transitions.

Application. Psychologists may help foster resilience in relationships by addressing issues specific to partners of TGNC people. Psychologists may provide support to partners of TGNC people who are having difficulty with their partner's evolving gender identity or transition, or are experiencing others having difficulty with the partner's transition. Partner peer support groups may be especially helpful in navigating internalized antitrans prejudice, shame, resentment, and relationship concerns related to a partner's gender transition. Meeting or knowing other TGNC people, other partners of TGNC people, and couples who have successfully navigated transition may also help TGNC people and their partners and serve as a protective factor (Brown, 2007). When TGNC status is disclosed during an existing relationship, psychologists may help couples explore which relationship dynamics they want to preserve and which they might like to change.

In working with psychologists, TGNC people may explore a range of issues in their relationships and sexuality (dickey et al., 2012), including when and how to come out to current or potential romantic and sexual partners, communicating their sexual desires, renegotiating intimacy that may be lost during the TGNC partner's transition, adapting to bodily changes caused by hormone use or surgery, and exploring boundaries regarding touch, affection, and safer sex practices (Iantaffi & Bockting, 2011; Sevelius, 2009). TGNC people may experience increased sexual self-efficacy through transition. Although psychologists may aid partners in understanding a TGNC person's transition decisions, TGNC people may also benefit from help in cultivating awareness of the ways in which these decisions influence the lives of loved ones.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Rationale. Psychologists work with TGNC people across the life span to address parenting and family issues (Kenagy & Hsieh, 2005). There is evidence that many TGNC people have and want children (Wierckx et al., 2012). Some TGNC people conceive a child through sexual intercourse, whereas others may foster, adopt, pursue surrogacy, or employ assisted reproductive technologies, such as sperm or egg donation, to build or expand a family (De Sutter, Kira, Verschoor, & Hotimsky, 2002). Based on a small body of research to date, there is no indication that children of TGNC parents suffer long-term negative impacts directly related to parental gender change (R. Green, 1978, 1988; White & Ettner, 2004). TGNC people may find it both challenging to find medical providers who are willing to offer them reproductive treatment and to afford the cost (Coleman et al., 2012). Similarly, adoption can be quite costly, and some TGNC people may find it challenging to find foster care or adoption agencies that will work with them in a nondiscriminatory manner. Current or past use of hormone therapy may limit fertility and restrict a TGNC person's reproductive options (Darnery, 2008; Wierckx et al., 2012). Other TGNC people may have children or families before coming out as TGNC or beginning a gender transition.

TGNC people may present with a range of parenting and family-building concerns. Some will seek support to address issues within preexisting family systems, some will explore the creation or expansion of a family, and some will need to make decisions regarding potential fertility issues related to hormone therapy, pubertal suppression, or surgical transition. The medical and/or social transition of a TGNC parent may shift family dynamics, creating challenges and opportunities for partners, children, and other family members. One study of therapists' reflections on their experiences with TGNC clients suggested that family constellation and the parental relationship was more significant for children than the parent's social and/or medical

transition itself (White & Ettner, 2004). Although research has not documented that the transitions of TGNC people have an effect on their parenting abilities, preexisting partnerships or marriages may not survive the disclosure of a TGNC identity or a subsequent transition (dickey et al., 2012). This may result in divorce or separation, which may affect the children in the family. A positive relationship between parents, regardless of marital status, has been suggested to be an important protective factor for children (Amato, 2001; White & Ettner, 2007). This seems to be the case especially when children are reminded of the parent's love and assured of the parent's continued presence in their life (White & Ettner, 2007). Based on a small body of literature available, it is generally the case that younger children are best able to incorporate the transition of a parent, followed by adult children, with adolescents generally having the most difficulty (White & Ettner, 2007). If separated or divorced from their partners or spouses, TGNC parents may be at risk for loss of custody or visitation rights because some courts presume that there is a nexus between their gender identity or gender expression and parental fitness (Flynn, 2006). This type of prejudice is especially common for TGNC people of color (Grant et al., 2011).

Application. Psychologists are encouraged to attend to the parenting and family-building concerns of TGNC people. When working with TGNC people who have previous parenting experience, psychologists may help TGNC people identify how being a parent may influence decisions to come out as TGNC or to begin a transition (Freeman, Tasker, & Di Ceglie, 2002; Grant et al., 2011; Wierckx et al., 2012). Some TGNC people may choose to delay disclosure until their children have grown and left home (Bethea & McCollum, 2013). Clinical guidelines jointly developed by a Vancouver, British Columbia, TGNC community organization and a health care provider organization encourage psychologists and other mental health providers working with TGNC people to plan for disclosure to a partner, previous partner, or children, and to pay particular attention to resources that assist TGNC people to discuss their identity with children of various ages in developmentally appropriate ways (Bockting et al., 2006). Lev (2004) uses a developmental stage framework for the process that family members are likely to go through in coming to terms with a TGNC family member's identity that some psychologists may find helpful. Awareness of peer support networks for spouses and children of TGNC people can also be helpful (e.g., PFLAG, TransYouth Family Allies). Psychologists may provide family counseling to assist a family in managing disclosure, improve family functioning, and maintain family involvement of the TGNC person, as well as aiding the TGNC person in attending to the ways that their transition process has affected their family members (Samons, 2008). Helping parents to continue to work together to focus on the needs of their children and to maintain family bonds is likely to lead to the best results for the children (White & Ettner, 2007).

For TGNC people with existing families, psychologists may support TGNC people in seeking legal counsel regarding parental rights in adoption or custody. Depending on the situation, this may be desirable even if the TGNC parent is biologically related to the child (Minter & Wald, 2012). Although being TGNC is not a legal impediment to adoption in the United States, there is the potential for overt and covert discrimination and barriers, given the widespread prejudice against TGNC people. The question of whether to disclose TGNC status on an adoption application is a personal one, and a prospective TGNC parent would benefit from consulting a lawyer for legal advice, including what the laws in their jurisdiction say about disclosure. Given the extensive background investigation frequently conducted, it may be difficult to avoid disclosure. Many lawyers favor disclosure to avoid any potential legal challenges during the adoption process (Minter & Wald, 2012).

In discussing family-building options with TGNC people, psychologists are encouraged to remain aware that some of these options require medical intervention and are not available everywhere, in addition to being quite costly (Coleman et al., 2012). Psychologists may work with clients to manage feelings of loss, grief, anger, and resentment that may arise if TGNC people are unable to access or afford the services they need for building a family (Bockting et al., 2006; De Sutter et al., 2002).

When TGNC people consider beginning hormone therapy, psychologists may engage them in a conversation about the possibly permanent effects on fertility to better prepare TGNC people to make a fully informed decision. This may be of special importance with TGNC adolescents and young adults who often feel that family planning or loss of fertility is not a significant concern in their current daily lives, and therefore disregard the long-term reproductive implications of hormone therapy or surgery (Coleman et al., 2012). Psychologists are encouraged to discuss contraception and safer sex practices with TGNC people, given that they may still have the ability to conceive even when undergoing hormone therapy (Bockting, Robinson, & Rosser, 1998). Psychologists may play a critical role in educating TGNC adolescents and young adults and their parents about the long-term effects of medical interventions on fertility and assist them in offering informed consent prior to pursuing such interventions. Although hormone therapy may limit fertility (Coleman et al., 2012), psychologists may encourage TGNC people to refrain from relying on hormone therapy as the sole means of birth control, even when a person has amenorrhea (Gorton & Grubb, 2014). Education on safer sex practices may also be important, as some segments of the TGNC community (e.g., trans women and people of color) are especially vulnerable to sexually transmitted infections and have been shown to have high prevalence and incidence rates of HIV infection (Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Nemoto, Operario, Keatley, Han, & Soma, 2004).

Depending on the timing and type of options selected, psychologists may explore the physical, social, and emotional implications should TGNC people choose to delay or

stop hormone therapy, undergo fertility treatment, or become pregnant. Psychological effects of stopping hormone therapy may include depression, mood swings, and reactions to the loss of physical masculinization or feminization facilitated by hormone therapy (Coleman et al., 2012). TGNC people who choose to halt hormone therapy during attempts to conceive or during a pregnancy may need additional psychological support. For example, TGNC people and their families may need help in managing the additional antitrans prejudice and scrutiny that may result when a TGNC person with stereotypically masculine features becomes visibly pregnant. Psychologists may also assist TGNC people in addressing their loss when they cannot engage in reproductive activities that are consistent with their gender identity, or when they encounter barriers to conceiving, adopting, or fostering children not typically faced by other people (Vanderburgh, 2007). Psychologists are encouraged to assess the degree to which reproductive health services are TGNC-affirmative prior to referring TGNC people to them. Psychologists are also encouraged to provide TGNC-affirmative information to reproductive health service personnel when there is a lack of trans-affirmative knowledge.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Rationale. Collaboration across disciplines can be crucial when working with TGNC people because of the potential interplay of biological, psychological, and social factors in diagnosis and treatment (Hendricks & Testa, 2012). The challenges of living with a stigmatized identity and the need of many TGNC people to transition, socially and/or medically, may call for the involvement of health professionals from various disciplines, including psychologists, psychiatrists, social workers, primary health care providers, endocrinologists, nurses, pharmacists, surgeons, gynecologists, urologists, electrologists, speech therapists, physical therapists, pastoral counselors and chaplains, and career or educational counselors. Communication, cooperation, and collaboration will ensure optimal coordination and quality of care. Just as psychologists often refer TGNC people to medical providers for assessment and treatment of medical issues, medical providers may rely on psychologists to assess readiness and assist TGNC clients to prepare for the psychological and social aspects of transition before, during, and after medical interventions (Coleman et al., 2012; Hembree et al., 2009; Lev, 2009). Outcome research to date supports the value and effectiveness of an interdisciplinary, collaborative approach to TGNC-specific care (see Coleman et al., 2012 for a review).

Application. Psychologists' collaboration with colleagues in medical and associated health disciplines involved in TGNC clients' care (e.g., hormonal and surgical treatment, primary health care; Coleman et al., 2012; Lev, 2009) may take many forms and should occur in a timely manner that does not complicate access to needed services (e.g., considerations of wait time). For example, a psychologist working with a trans man who has a diagnosis of bipolar disorder may need to coordinate with his primary care provider and psychiatrist to adjust his hormone levels and psychiatric medications, given that testosterone can have an activating effect, in addition to treating gender dysphoria. At a basic level, collaboration may entail the creation of required documentation that TGNC people present to surgeons or medical providers to access gender-affirming medical interventions (e.g., surgery, hormone therapy; Coleman et al., 2012). Psychologists may offer support, information, and education to interdisciplinary colleagues who are unfamiliar with issues of gender identity and gender expression to assist TGNC people in obtaining TGNC-affirmative care (Holman & Goldberg, 2006; Lev, 2009). For example, a psychologist who is assisting a trans woman with obtaining gender-affirming surgery may, with her consent, contact her new gynecologist in preparation for her first medical visit. This contact could include sharing general information about her gender history and discussing how both providers could most affirmatively support appropriate health checks to ensure her best physical health (Holman & Goldberg, 2006).

Psychologists in interdisciplinary settings could also collaborate with medical professionals prescribing hormone therapy by educating TGNC people and ensuring TGNC people are able to make fully informed decisions prior to starting hormone treatment (Coleman et al., 2012; Deutsch, 2012; Lev, 2009). Psychologists working with children and adolescents play a particularly important role on the interdisciplinary team due to considerations of cognitive and social development, family dynamics, and degree of parental support. This role is especially crucial when providing psychological evaluation to determine the appropriateness and timeliness of a medical intervention. When psychologists are not part of an interdisciplinary setting, especially in isolated or rural communities, they can identify interdisciplinary colleagues with whom they may collaborate and/or refer (Walinsky & Whitcomb, 2010). For example, a rural psychologist could identify a trans-affirmative pediatrician in a surrounding area and collaborate with the pediatrician to work with parents raising concerns about their TGNC and questioning children and adolescents.

In addition to working collaboratively with other providers, psychologists who obtain additional training to specialize in work with TGNC people may also serve as consultants in the field (e.g., providing additional support to providers working with TGNC people or assisting school and workplaces with diversity training). Psychologists who have expertise in working with TGNC people may play a consultative role with providers in inpatient settings seeking to provide affirmative care to TGNC clients. Psychologists may also collaborate with social service colleagues to provide TGNC people with affirmative referrals related to housing, financial support, vocational/educational counseling and training, TGNC-affirming religious or spiritual communities, peer support, and other community resources (Gehi & Arkles, 2007). This collaboration might also in-

clude assuring that TGNC people who are minors in the care of the state have access to culturally appropriate care.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Rationale. Historically, in a set of demographic questions, psychological research has included one item on either sex or gender, with two response options—male and female. This approach wastes an opportunity to increase knowledge about TGNC people for whom neither option may fit their identity, and runs the risk of alienating TGNC research participants (IOM, 2011). For example, there is little knowledge about HIV prevalence, risks, and prevention needs of TGNC people because most of the research on HIV has not included demographic questions to identify TGNC participants within their samples. Instead, TGNC people have been historically subsumed within larger demographic categories (e.g., men who have sex with men, women of color), rendering the impact of the HIV epidemic on the TGNC population invisible (Herbst et al., 2008). Scholars have noted that this invisibility fails to draw attention to the needs of TGNC populations that experience the greatest health disparities, including TGNC people who are of color, immigrants, low income, homeless, veterans, incarcerated, live in rural areas, or have disabilities (Bauer et al., 2009; Hanssmann, Morrison, Russian, Shiu-Thornton, & Bowen, 2010; Shipherd et al., 2012; Walinsky & Whitcomb, 2010).

There is a great need for more research to inform practice, including affirmative treatment approaches with TGNC people. Although sufficient evidence exists to support current standards of care (Byne et al., 2012; Coleman et al., 2012), much is yet to be learned to optimize quality of care and outcome for TGNC clients, especially as it relates to the treatment of children (IOM, 2011; Mikalson et al., 2012). In addition, some research with TGNC populations has been misused and misinterpreted, negatively affecting TGNC people's access to health services to address issues of gender identity and gender expression (Namaste, 2000). This has resulted in justifiable skepticism and suspicion in the TGNC community when invited to participate in research initiatives. In accordance with the APA ethics code (APA, 2010), psychologists conduct research and distribute research findings with integrity and respect for their research participants. As TGNC research increases, some TGNC communities may experience being oversampled in particular geographic areas and/or TGNC people of color may not be well-represented in TGNC studies (Hwahng & Lin, 2009; Namaste, 2000).

Application. All psychologists conducting research, even when not specific to TGNC populations, are encouraged to provide a range of options for capturing demographic information about TGNC people so that TGNC people may be included and accurately represented (Conron et al., 2008; Deutsch et al., 2013). One group of experts has recommended that population research, and especially government-sponsored surveillance research, use a two-step method, first asking for sex assigned at birth, and then following with a question about gender identity (GenIUSS, 2013). For research focused on TGNC people, including questions that assess both sex assigned at birth and current gender identity allows the disaggregation of subgroups within the TGNC population and has the potential to increase knowledge of differences within the population. In addition, findings about one subgroup of TGNC people may not apply to other subgroups. For example, results from a study of trans women of color with a history of sex work who live in urban areas (Nemoto, Operario, Keatley, & Villegas, 2004) may not generalize to all TGNC women of color or to the larger TGNC population (Bauer, Travers, Scanlon, & Coleman, 2012; Operario et al., 2008).

In conducting research with TGNC people, psychologists will confront the challenges associated with studying a relatively small, geographically dispersed, diverse, stigmatized, hidden, and hard-to-reach population (IOM, 2011). Because TGNC individuals are often hard to reach (IOM, 2011) and TGNC research is rapidly evolving, it is important to consider the strengths and limitations of the methods that have been or may be used to study the TGNC population, and to interpret and represent findings accordingly. Some researchers have strongly recommended collaborative research models (e.g., participatory action research) in which TGNC community members are integrally involved in these research activities (Clements-Nolle & Bachrach, 2003; Singh, Richmond, & Burnes, 2013). Psychologists who seek to educate the public by communicating research findings in the popular media will also confront challenges, because most journalists have limited knowledge about the scientific method and there is potential for the media to misinterpret, exploit, or sensationalize findings (Garber, 1992; Namaste, 2000).

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

Rationale. The *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010) include gender identity as one factor for which psychologists may need to obtain training, experience, consultation, or supervision in order to ensure their competence (APA, 2010). In addition, when APA-accredited programs are required to demonstrate a commitment to cultural and individual diversity, gender identity is specifically included (APA, 2015). Yet surveys of TGNC people suggest that many mental health care providers lack even basic knowledge and skills required to offer trans-affirmative care (Bradford et al., 2007; O'Hara, Dispenza, Brack, & Blood, 2013; Xavier et al., 2005). The APA Task Force on Gender Identity and Gender Variance (2009) projected that many, if not most, psychologists and graduate psychology students will at some point encounter TGNC people among their clients, colleagues, and trainees. Yet professional education and training in psychology includes little or no preparation for

working with TGNC people (Anton, 2009; APA TFGIGV, 2009), and continuing professional education available to practicing mental health clinicians is also scant (Lurie, 2005). Only 52% percent of psychologists and graduate students who responded to a survey conducted by an APA Task Force reported having had the opportunity to learn about TGNC issues in school; of those respondents, only 27% reported feeling adequately familiar with gender concerns (n = 294; APA TFGIGV, 2009).

Training on gender identity in professional psychology has frequently been subsumed under discussions of sexual orientation or in classes on human sexuality. Some scholars have suggested that psychologists and students may mistakenly believe that they have obtained adequate knowledge and awareness about TGNC people through training focused on LGB populations (Harper & Schneider, 2003). However, Israel and colleagues have found important differences between the therapeutic needs of TGNC people and those of LGB people in the perceptions of both clients and providers (Israel et al., 2008; Israel, Walther, Gorcheva, & Perry, 2011). Nadal and colleagues have suggested that the absence of distinct, accurate information about TGNC populations in psychology training not only perpetuates misunderstanding and marginalization of TGNC people by psychologists but also contributes to continued marginalization of TGNC people in society as a whole (Nadal et al., 2010, 2012).

Application. Psychologists strive to continue their education on issues of gender identity and gender expression with TGNC people as a foundational component of affirmative psychological practice. In addition to these guidelines, which educators may use as a resource in developing curricula and training experiences, ACA (2010) has also adopted a set of competencies that may be a helpful resource for educators. In addition to including TGNC people and their issues in foundational education in health service psychology (e.g., personality development, multiculturalism, research methods), some psychology programs may also provide coursework and training for students interested in developing more advanced expertise on issues of gender identity and gender expression.

Because of the high level of societal ignorance and stigma associated with TGNC people, ensuring that psychological education, training, and supervision is affirmative, and does not sensationalize (Namaste, 2000), exploit, or pathologize TGNC people (Lev, 2004), will require care on the part of educators. Students will benefit from support from their educators in developing a professional, nonjudgmental attitude toward people who may have a different experience of gender identity and gender expression from their own. A number of training resources have been published that may be helpful to psychologists in integrating information about TGNC people into the training they offer (e.g., Catalano, McCarthy, & Shlasko, 2007; Stryker, 2008; Wentling, Schilt, Windsor, & Lucal, 2008). Because most psychologists have had little or no training on TGNC populations and do not perceive themselves as having sufficient understanding of issues related to gender identity and gender expression (APA TFGIGV, 2009), psychologists with relevant expertise are encouraged to develop and distribute continuing education and training to help to address these gaps. Psychologists providing education can incorporate activities that increase awareness of cisgender privilege, antitrans prejudice and discrimination, host a panel of TGNC people to offer personal perspectives, or include narratives of TGNC people in course readings (ACA, 2010). When engaging these approaches, it is important to include a wide variety of TGNC experiences to reflect the inherent diversity within the TGNC community.

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Appendix A
Definitions

Terminology within the health care field and transgender and gender nonconforming (TGNC) communities is constantly evolving (Coleman et al., 2012). The evolution of terminology has been especially rapid in the last decade, as the profession's awareness of gender diversity has increased, as more literature and research in this area has been published, and as voices of the TGNC community have strengthened. Some terms or definitions are not universally accepted, and there is some disagreement among professionals and communities as to the "correct" words or definitions, depending on theoretical orientation, geographic region, generation, or culture, with some terms seen as affirming and others as outdated or demeaning. American Psychological Association (APA) Task Force for *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* developed the definitions below by reviewing existing definitions put forward by professional organizations (e.g., APA Task Force on Gender Identity and Gender Variance, 2009; the Institute of Medicine, 2011; and the World Professional Association for Transgender Health [Coleman et al., 2012]), health care agencies serving TGNC clients (e.g., Fenway Health Center), TGNC community resources (Gender Equity Resource Center, National Center for Transgender Equality), and professional literature. Psychologists are encouraged to refresh their knowledge and familiarity with evolving terminology on a regular basis as changes emerge in the community and/or the professional literature. The definitions below include terms frequently used within the *Guidelines*, by the TGNC community, and within professional literature.

Ally: a cisgender person who supports and advocates for TGNC people and/or communities.

(*Appendices continue*)

Antitrans prejudice (transprejudice, transnegativity, transphobia): prejudicial attitudes that may result in the devaluing, dislike, and hatred of people whose gender identity and/or gender expression do not conform to their sex assigned at birth. Antitrans prejudice may lead to discriminatory behaviors in such areas as employment and public accommodations, and may lead to harassment and violence. When TGNC people hold these negative attitudes about themselves and their gender identity, it is called *internalized transphobia* (a construct analogous to internalized homophobia). Transmisogyny describes a simultaneous experience of sexism and antitrans prejudice with particularly adverse effects on trans women.

Cisgender: an adjective used to describe a person whose gender identity and gender expression align with sex assigned at birth; a person who is not TGNC.

Cisgenderism: a systemic bias based on the ideology that gender expression and gender identities are determined by sex assigned at birth rather than self-identified gender identity. Cisgenderism may lead to prejudicial attitudes and discriminatory behaviors toward TGNC people or to forms of behavior or gender expression that lie outside of the traditional gender binary.

Coming out: a process by which individuals affirm and actualize a stigmatized identity. Coming out as TGNC can include disclosing a gender identity or gender history that does not align with sex assigned at birth or current gender expression. Coming out is an individual process and is partially influenced by one's age and other generational influences.

Cross dressing: wearing clothing, accessories, and/or make-up, and/or adopting a gender expression not associated with a person's assigned sex at birth according to cultural and environmental standards (Bullough & Bullough, 1993). Cross-dressing is not always reflective of gender identity or sexual orientation. People who cross-dress may or may not identify with the larger TGNC community.

Disorders of sex development (DSD, Intersex): term used to describe a variety of medical conditions associated with atypical development of an individual's physical sex characteristics (Hughes, Houk, Ahmed, & Lee, 2006). These conditions may involve differences of a person's internal and/or external reproductive organs, sex chromosomes, and/or sex-related hormones that may complicate sex assignment at birth. DSD conditions may be considered variations in biological diversity rather than disorders (M. Diamond, 2009); therefore some prefer the terms *intersex*, *intersexuality*, or *differences in sex development* rather than "disorders of sex development" (Coleman et al., 2012).

Drag: the act of adopting a gender expression, often as part of a performance. Drag may be enacted as a political comment on gender, as parody, or as entertainment, and is not necessarily reflective of gender identity.

Female-to-male (FTM): individuals assigned a female sex at birth who have changed, are changing, or wish to change their body and/or gender identity to a more masculine body or gender identity. FTM persons are also often referred to as *transgender men*, *transmen*, or *trans men*.

Gatekeeping: the role of psychologists and other mental health professionals of evaluating a TGNC person's eligibility and readiness for hormone therapy or surgery according to the Standards of Care set forth by the World Professional Association for Transgender Health (Coleman et al., 2012). In the past, this role has been perceived as limiting a TGNC adult's autonomy and contributing to mistrust between psychologists and TGNC clients. Current approaches are sensitive to this history and are more affirming of a TGNC adult's autonomy in making decisions with regard to medical transition (American Counseling Association, 2010; Coleman et al., 2012; Singh & Burnes, 2010).

Gender-affirming surgery (sex reassignment surgery or gender reassignment surgery): surgery to change primary and/or secondary sex characteristics to better align a person's physical appearance with their gender identity. Gender-affirming surgery can be an important part of medically necessary treatment to alleviate gender dysphoria and may include mastectomy, hysterectomy, metoidioplasty, phalloplasty, breast augmentation, orchiectomy, vaginoplasty, facial feminization surgery, and/or other surgical procedures.

Gender binary: the classification of gender into two discrete categories of boy/man and girl/woman.

Gender dysphoria: discomfort or distress related to incongruence between a person's gender identity, sex assigned at birth, gender identity, and/or primary and secondary sex characteristics (Knudson, De Cuypere, & Bockting, 2010). In 2013, the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM–5*; American Psychiatric Association, 2013) adopted the term *gender dysphoria* as a diagnosis characterized by "a marked incongruence between" a person's gender assigned at birth and gender identity (American Psychiatric Association, 2013, p. 453). Gender dysphoria replaced the diagnosis of gender identity disorder (GID) in the previous version of the *DSM* (American Psychiatric Association, 2000).

Gender expression: the presentation of an individual, including physical appearance, clothing choice and accessories, and behaviors that express aspects of gender identity or role. Gender expression may or may not conform to a person's gender identity.

(*Appendices continue*)

Gender identity: a person's deeply felt, inherent sense of being a boy, a man, or male; a girl, a woman, or female; or an alternative gender (e.g., genderqueer, gender nonconforming, gender neutral) that may or may not correspond to a person's sex assigned at birth or to a person's primary or secondary sex characteristics. Because gender identity is internal, a person's gender identity is not necessarily visible to others. "Affirmed gender identity" refers to a person's gender identity after coming out as TGNC or undergoing a social and/or medical transition process.

Gender marker: an indicator (M, F) of a person's sex or gender found on identification (e.g., driver's license, passport) and other legal documents (e.g., birth certificate, academic transcripts).

Gender nonconforming (GNC): an adjective used as an umbrella term to describe people whose gender expression or gender identity differs from gender norms associated with their assigned birth sex. Subpopulations of the TGNC community can develop specialized language to represent their experience and culture, such as the term "masculine of center" (MOC; Cole & Han, 2011) that is used in communities of color to describe one's GNC identity.

Gender questioning: an adjective to describe people who may be questioning or exploring their gender identity and whose gender identity may not align with their sex assigned at birth.

Genderqueer: a term to describe a person whose gender identity does not align with a binary understanding of gender (i.e., a person who does not identify fully as either a man or a woman). People who identify as genderqueer may redefine gender or decline to define themselves as gendered altogether. For example, people who identify as genderqueer may think of themselves as both man and woman (bigender, pangender, androgyne); neither man nor woman (genderless, gender neutral, neutrois, agender); moving between genders (genderfluid); or embodying a third gender.

Gender role: refers to a pattern of appearance, personality, and behavior that, in a given culture, is associated with being a boy/man/male or being a girl/woman/female. The appearance, personality, and behavior characteristics may or may not conform to what is expected based on a person's sex assigned at birth according to cultural and environmental standards. Gender role may also refer to the *social* role in which one is living (e.g., as a woman, a man, or another gender), with some role characteristics conforming and others not conforming to what is associated with girls/women or boys/men in a given culture and time.

Hormone therapy (gender-affirming hormone therapy, hormone replacement therapy): the use of hormones to masculinize or feminize a person's body to better align that person's physical characteristics with their gender identity. People wishing to feminize their body receive antiandrogens and/or estrogens; people wishing to masculinize their body receive testosterone. Hormone therapy may be an important part of medically necessary treatment to alleviate gender dysphoria.

Male-to-female (MTF): individuals whose assigned sex at birth was male and who have changed, are changing, or wish to change their body and/or gender role to a more feminized body or gender role. MTF persons are also often referred to as *transgender women*, *transwomen*, or *trans women*.

Passing: the ability to blend in with cisgender people without being recognized as transgender based on appearance or gender role and expression; being perceived as cisgender. Passing may or may not be a goal for all TGNC people.

Puberty suppression (puberty blocking, puberty delaying therapy): a treatment that can be used to temporarily suppress the development of secondary sex characteristics that occur during puberty in youth, typically using gonadotropin-releasing hormone (GnRH) analogues. Puberty suppression may be an important part of medically necessary treatment to alleviate gender dysphoria. Puberty suppression can provide adolescents time to determine whether they desire less reversible medical intervention and can serve as a diagnostic tool to determine if further medical intervention is warranted.

Sex (sex assigned at birth): sex is typically assigned at birth (or before during ultrasound) based on the appearance of external genitalia. When the external genitalia are ambiguous, other indicators (e.g., internal genitalia, chromosomal and hormonal sex) are considered to assign a sex, with the aim of assigning a sex that is most likely to be congruent with the child's gender identity (MacLaughlin & Donahoe, 2004). For most people, gender identity is congruent with sex assigned at birth (see *cisgender*); for TGNC individuals, gender identity differs in varying degrees from sex assigned at birth.

Sexual orientation: a component of identity that includes a person's sexual and emotional attraction to another person and the behavior and/or social affiliation that may result from this attraction. A person may be attracted to men, women, both, neither, or to people who are genderqueer, androgynous, or have other gender identities. Individuals may identify as lesbian, gay, heterosexual, bisexual, queer, pansexual, or asexual, among others.

Stealth (going stealth): a phrase used by some TGNC people across the life span (e.g., children, adolescents) who choose to make a transition in a new environment (e.g., school) in their affirmed gender without openly sharing their identity as a TGNC person.

(*Appendices continue*)

TGNC: an abbreviation used to refer to people who are transgender or gender nonconforming.

Trans: common short-hand for the terms transgender, transsexual, and/or gender nonconforming. Although the term "trans" is commonly accepted, not all transsexual or gender nonconforming people identify as trans.

Trans-affirmative: being respectful, aware and supportive of the needs of TGNC people.

Transgender: an adjective that is an umbrella term used to describe the full range of people whose gender identity and/or gender role do not conform to what is typically associated with their sex assigned at birth. Although the term "transgender" is commonly accepted, not all TGNC people self-identify as transgender.

Transgender man, trans man, or transman: a person whose sex assigned at birth was female, but who identifies as a man (see FTM).

Transgender woman, trans woman, or transwoman: a person whose sex assigned at birth was male, but who identifies as a woman (see MTF).

Transition: a process some TGNC people progress through when they shift toward a gender role that differs from the one associated with their sex assigned at birth. The length, scope, and process of transition are unique to each person's life situation. For many people, this involves developing a gender role and expression that is more aligned with their gender identity. A transition typically occurs over a period of time; TGNC people may proceed through a social transition (e.g., changes in gender expression, gender role, name, pronoun, and gender marker) and/or a medical transition (e.g., hormone therapy, surgery, and/or other interventions).

Transsexual: term to describe TGNC people who have changed or are changing their bodies through medical interventions (e.g., hormones, surgery) to better align their bodies with a gender identity that is different than their sex assigned at birth. Not all people who identify as transsexual consider themselves to be TGNC. For example, some transsexual individuals identify as female or male, without identifying as TGNC. Transsexualism is used as a medical diagnosis in the World Health Organization's (2015) International Classification of Diseases version 10.

Two-spirit: term used by some Native American cultures to describe people who identify with both male and female gender roles; this can include both gender identity and sexual orientation. Two-spirit people are often respected and carry unique spiritual roles for their community.

Appendix B
Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gender expression may affect the quality of care they provide to TGNC people and their families.

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Guideline 7. Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

(*Appendices continue*)

Life Span Development

Guideline 8. Psychologists working with gender-questioning and TGNC youth understand the different developmental needs of children and adolescents and that not all youth will persist in a TGNC identity into adulthood.

Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

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TAB 176-6

Pl. Trial Ex. 046

AMERICAN PSYCHOLOGICAL ASSOCIATION

APA RESOLUTION on Gender Identity Change Efforts

FEBRUARY 2021

The foundational professional guideline for working with gender diverse persons acknowledges that, "Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth." (APA, 2015, p. 834). Gender identity refers to "a person's deep felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; [or another] gender" (APA, 2015, p. 862). While gender refers to the trait characteristics and behaviors culturally associated with one's sex assigned at birth, in some cases, gender may be distinct from the physical markers of biological sex (e.g., genitals, chromosomes). Gender identity is also distinct from gender expression, which refers to "the presentation of an individual including physical appearance, clothing choice and accessories, and behaviors that express aspects of gender identity" (APA, 2015, p. 861). Cisgender refers to "a person whose gender identity aligns with sex assigned at birth" (e.g., an individual assigned female at birth who identifies as a woman/girl; APA, 2015, p. 861). Transgender is "an umbrella term used to describe the full range of people whose gender identity and/or gender role do not conform to what is typically associated with their sex assigned at birth" (APA, 2015, p. 863). For the purpose of this resolution, we are using a broad definition of transgender to include transgender women/girls, transgender men/boys, nonbinary individuals (i.e., people who may identify as a gender other than a woman/girl or a man/boy), and any individual who articulates a gender identity different from societal expectations based on their sex assigned at birth.

Some transgender and gender nonbinary individuals seek gender-affirming medical care (e.g., hormone therapy, surgery) while others do not. Similarly, some transgender and gender nonbinary individuals seek to change their gender marker and/or their name on legal documents, while others do not. In this resolution, we strive to be inclusive of all gender diversity regardless of a person's pursuance of social, medical, or legal transition.

The fields of psychiatry and psychology have a long history of pathologizing individuals and those who question their gender identity (Barkai, 2017; Benson, 2013; Bouman et al, 2014; Burke, 2011; Drescher, 2010; Nadal et al., 2010; Riggs et al. 2019). This history is informed by, and parallels, the larger Western and United States-based, medical-model, narratives that 1) define gender as binary and conflate it with physical markers, 2) define masculinity, and characteristics historically attributed to men/boys, as superior to femininity and characteristics historically attributed to women/girls, 3) create systems that confer privilege to cisgender people and label cisgender identities and expressions as normative, 4) discriminate against transgender and gender nonbinary individuals (Stryker, 2017).

Gender identity change efforts (GICE) refer to a range of techniques used by mental health professionals and non-professionals with the goal of changing gender identity, gender expression, or associated components of these to be in alignment with gender role behaviors that are stereotypically associated with sex assigned at birth, (Hill et al., 2010; SAMHSA, 2015). In addition to explicit attempts to change individuals' gender according to cisnormative pressures, GICE has also been a component of sexual orientation change efforts (SOCE). As intense focus on cisnormative conformity is a frequent characteristic of SOCE it is possible that authors in the literature describing sexual orientation change efforts misgendered their participants (Hipp et al., 2019). Moreover, "ex-gay" literature and discourse conceptualize gender diversity as a sin, a mental illness, and harmful, perpetuating cisgenderism and transmisogyny (Robinson & Spivey, 2019). Finally, Hipp et al. (2019) identified forms of GICE that are often not discussed in the psychological literature but that appear to disproportionately affect Black transgender and gender nonbinary individuals including violence, "church hurt" (i.e., religious or faith-based trauma), and gatekeeping from gender affirming care. These efforts may be referred to as "conversion therapies", "corrective" treatments, or "normalizing" therapies (Hill et al., 2010). However, to consider these techniques as therapies or treatments is inaccurate and inappropriate because, the incongruence between sex and gender in and of itself is not a mental disorder (World Health Organization, n.d.) so, any behavioral health or GICE technique or treatment that seeks to change an individual's gender identity or expression is not indicated; thus, any behavioral health or GICE effort that attempt to change an individual's gender identity or expression is inappropriate (Hill et al. 2010; SAMHSA, 2015).

With roots in this history, GICE are founded on the notion that any gender identity that is not concordant with sex assigned at birth is disordered, and that a cisgender identity is healthier, preferable, and superior to a transgender or gender nonbinary identity (Ansara & Hegarty, 2011; Hill et al., 2010; Robinson & Spivey, 2019).

GICE cause harm by reinforcing anti-transgender and anti-gender nonbinary stigma and discrimination (Turban et al., 2020); and by creating social pressure on an individual to conform to an

identity and/or presentation that may not be consistent with their sense of self (e.g., Bockting et al., 2013; Egan & Perry, 2001; Meyer, 2003; Nadal et al., 2012; Russell et al., 2012; Toomey et al., 2010; Sandfort et al., 2007). Furthermore, GICE are not supported by empirical evidence as effective practices for changing gender identity and are associated with psychological and social harm (Brinkman et al., 2014; Carr, 1998; Gagné & Tewksbury, 1998; Horn, 2007; Price et al., 2019; Smith & Leaper, 2006). The American Psychological Association (APA), as well as other healthcare organizations, (e.g., American Counseling Association, World Professional Association for Transgender Health) have established empirically-supported practice guidelines that encourage clinicians to use gender-affirming practices when addressing gender identity issues (ACA, 2010; APA, 2015; Coleman et al., 2012). Additionally, a number of national and international professional healthcare organizations have publicly warned against the harmful effects of GICE and SOCE (Sexual Orientation Change Efforts) by endorsing the United States Joint Statement Against Conversion Efforts (USJS, n.d.), including the American Academy of Family Physicians, American Academy of Nursing, American Association of Sexual Educators, Counselors and Therapists, American Counseling Association, American Medical Association, American Medical Student Association, American Psychoanalytic Association, The Association of LGBTQ Psychiatrists, Society for Affectional, Intersex, and Gender Expansive Identities, Clinical Social Work Association, GLMA: Health Professionals Advancing LGBTQ Equality, The Association of Lesbian, Gay, Bisexual, Transgender Addiction Professionals and their Allies, and the World Professional Association for Transgender Health. A growing number of states and municipalities have enacted laws that prohibit licensed mental health professionals from engaging in sexual orientation and gender identity change efforts with minors (Movement Advancement Project, n.d.)

GENDER DIVERSITY, STIGMA, AND DISCRIMINATION

WHEREAS diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy, incongruence between one's sex and gender is neither pathological nor a mental health disorder (APA, 2009, 2015; SAMHSA, 2015);

WHEREAS gender diverse individuals experience cissexist discrimination and prejudice throughout the lifespan and life domains (APA, 2009) including significant discrimination in healthcare settings (Burnes et al., 2016; Fredriksen-Goldsen et al., 2014; Grant et al., 2011; James et al., 2016; Johns et al, 2019; Lambda Legal, 2010; Macapagal et al., 2016; Reisner et al., 2015; White Hughto et al., 2015);

WHEREAS the practice of GICE reinforces stigma and discrimination against transgender and gender diverse people (Turban et al., 2020);

WHEREAS gender-related bias, victimization, discrimination, criminalization, and forced-gender conformity experienced by transgender and gender nonbinary people are associated with poor psychosocial outcomes, such as heightened psychological distress, compromised overall wellbeing, and disparities across various contexts (e.g., healthcare, schools/education, workplace, law) (Bockting et al., 2013; dickey et al., 2016; Egan & Perry, 2001; Meyer, 2003; Nadal et al., 2012; Russell et al., 2012; Hendricks & Testa, 2012; Toomey et al., 2010; Sandfort et al., 2007);

WHEREAS invalidation and rejection of transgender and gender nonbinary identities and diverse gender expressions by others (e.g., families, therapists, school personnel) are forms of discrimination, stigma, and victimization, which result in psychological distress (Bockting et al., 2013; D'Augelli et al., 2006; Egan & Perry, 2001; Hendricks & Testa, 2012; Hidalgo et al., 2015; Landolt et al., 2004; Meyer, 2003; Nadal et al., 2012; Price, et al., 2019; Roberts et al., 2012; Sandfort et al., 2007; Stotzer, 2012; Russell et al., 2012; Toomey et al., 2010; Truong et al., 2020a, 2020b; Zongrone et al., 2020);

GICE AND RISKS OF HARM

WHEREAS individuals who have experienced pressure or coercion to conform to their sex assigned at birth or therapy that was biased toward conformity to one's assigned sex at birth have reported harm resulting from these experience such as emotional distress, loss of relationships, and low self-worth (Brinkman et al., 2014; Carr, 1998; Gagné & Tewksbury, 1998; Horn, 2007; Price et al., 2019; Smith & Leaper, 2006);

WHEREAS in one study of a large online sample of LGBTQ young people, those who reported experiencing change efforts were more than twice as likely to report having attempted suicide and having multiple suicide attempts as those who did not experience change efforts, (Green et al., 2020);

WHEREAS GICE have not been shown to alleviate or resolve gender dysphoria (Bradley & Zucker, 1997; Cohen-Kettenis & Kuiper, 1984; Gelder & Marks, 1969; Greenson, 1964; Pauly, 1965, SAMHSA, 2015);

WHEREAS GICE can cause undue stress and suffering and interfere with healthy sexual and gender identity development (Hiestand & Levitt, 2005; SAMHSA, 2015);

WHEREAS GICE can reduce one's willingness to pursue future mental health treatment (Craig et al., 2017);

WHEREAS GICE often involves the promotion of stereotyped gender behaviors consistent with cultural expectations (Coleman et al., 2012; Hill et al., 2010);

WHEREAS GICE are associated with harmful social and emotional effects for many individuals, including but not limited to, the onset or increase of depression, anxiety, suicidality, loss of sexual feeling, impotence, deteriorated family relationships, a range of post-traumatic responses, and substance abuse (c.f. Burnes et al., 2016; Green et al., 2020; SAMHSA 2015 for a review; Turban et al., 2019);

WHEREAS diverse gender expressions and transgender and gender nonbinary identities are not mental disorders (American Psychiatric Association, 2013) and many transgender and gender nonbinary individuals lead satisfying lives and have healthy relationships (APA, 2015; SAMHSA, 2015);

GENDER AFFIRMING PRACTICES

WHEREAS transgender and gender nonbinary people whose gender has been affirmed report increased quality of life (Ainsworth & Spiegel, 2010; APA, 2015; Gerhardstein & Anderson, 2010; Kraemer et al., 2008; Newfield et al., 2006);

WHEREAS self-determination in defining one's gender identity is a source of resilience for transgender and gender nonbinary people and associated with improvements in wellbeing and reductions in psychological distress (Menvielle & Tuerk, 2002; Pickstone-Taylor, 2003; Rosenburg, 2002; Singh et al., 2011; Singh et al., 2014);

WHEREAS individuals who have experienced gender-affirming psychological and medical practices report improved psychological functioning, quality of life, treatment retention and engagement, and reductions in psychological distress, gender dysphoria, and maladaptive coping mechanisms (Austin & Craig, 2015; de Vries et al., 2014; Haas et al., 2011; Sevelius, 2013; White Hughto & Reisner, 2016);

WHEREAS professional consensus recommends affirming therapeutic interventions for transgender and gender nonbinary adults who request that a therapist engage in GICE, and for trans youth whose parents/guardians or other custodians (e.g., state, foster care) request that a therapist engage in GICE (American Counseling Association, 2009; APA, 2012; 2015; American Psychiatric Association, 2018; Byne et al., 2012; Edwards-Leeper et al., 2016);

WHEREAS affirming therapeutic practices and guidelines recommend that the therapist should remain objective and nonjudgmental to the outcome, focusing on empowering the client to be active in exploring, discovering, and understanding their own identity (American Counseling Association, 2009; APA, 2012; 2015; American Psychiatric Association, 2018; Byne et al., 2012; Edwards-Leeper et al., 2016);

APA POLICY

WHEREAS APA opposes discrimination on the basis of gender identity, gender expression, and transgender and gender nonbinary identities, and actively opposes the adoption of discriminatory legislation (APA, 2008);

WHEREAS APA supports the passage of laws and policies protecting the legal rights and freedoms of transgender and gender nonbinary people, regardless of gender identity or expression (APA, 2008);

WHEREAS Psychologists' work is based upon established scientific and professional knowledge of the discipline. (APA, 2017b, p. 5);

WHEREAS APA recognizes that psychologists work is based upon Respect for People's Rights and Dignity (Principle E), Avoiding Harm (3.04), and Unfair Discrimination (3.01; APA, 2017b);

WHEREAS gender affirming psychotherapy is founded in clinical practice guidelines, and harm has not been identified for any of these gender-affirming treatment practices (APA, 2015, 2017b; Byne et al., 2012);

WHEREAS the APA policy and practice guidelines (e.g., Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality; Guidelines for Psychological Practice with Transgender and Gender Nonconforming People) affirm that psychologists do not engage in discriminatory or biased practices and urge psychologists to take a leadership role in preventing discrimination towards transgender and gender diverse people (APA, 2009, 2015, 2017a);

WHEREAS APA's 2005 Policy Statement on Evidence-Based Practice in Psychology defines evidence-based practice as the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences (APA, 2005);

BE IT THEREFORE RESOLVED that consistent with the APA definition of evidence-based practice (APA, 2005), the APA affirms that scientific evidence and clinical experience indicate that GICE put individuals at significant risk of harm;

BE IT FURTHER RESOLVED that the APA opposes GICE because such efforts put individuals at significant risk of harm and encourages individuals, families, health professionals, and organizations to avoid GICE;

BE IT FURTHER RESOLVED that APA opposes the idea that incongruence between sex and gender is a mental disorder (Hill et al., 2010; SAMHSA, 2015; WHO).

BE IT FURTHER RESOLVED that after reviewing scientific evidence on GICE harm, affirmative treatments, and professional practice guidelines, the APA affirms GICE are associated with reported harm.

BE IT FURTHER RESOLVED that the APA opposes GICE because of their association with harm.

BE IT FURTHER RESOLVED that Transgender and gender nonbinary identities, as well as other gender identities that transcend culturally prescriptive binary notions of gender, represent normal variations in human expression of gender.

BE IT FURTHER RESOLVEDthat neither transgender or gender nonbinary identities nor the pursuit of gender-affirming medical care constitutes evidence of a mental disorder.

BE IT FURTHER RESOLVED that APA opposes portrayals of transgender and gender nonbinary people as mentally ill because of their gender identities and expressions.

BE IT FURTHER RESOLVED that evidence supports psychologists in their professional roles to use affirming and culturally relevant approaches with individuals of diverse gender expressions and identities.

BE IT FURTHER RESOLVED that APA is committed to promoting accurate scientific data regarding gender identity and expression in its own policy, public advocacy, judicial proceedings, media, and public opinion;

BE IT FURTHER RESOLVED that APA encourages collaboration between and among individuals and organizations to promote the wellbeing of transgender and gender nonbinary people;

BE IT FURTHER RESOLVED that the APA encourages psychologists to be aware of multiple and intersecting factors in identity, such as sex assigned at birth, gender expression, gender identity, age, race, ethnicity, religion, spirituality, socioeconomic status, disability, national origin, and sexual orientation in conceptualization, treatment, research, and teaching about transgender and gender nonbinary people;

BE IT FURTHER RESOLVED that the APA opposes the dissemination of inaccurate information about gender identity, gender expression, and the efficacy of GICE, including the claim that gender identity can be changed through treatment, the characterization of transgender or gender nonbinary identity as a mental disorder and the promotion of treatments that prescribe gender identity or expression consistent with one's birth-assigned sex as effective for clients with gender dysphoria;

BE IT FURTHER RESOLVED that APA encourages the development and dissemination of evidence-based, multiculturally-informed, and gender affirmative educational resources that inform psychologists, the community and education and mental health institutions about the harms of GICE;

BE IT FURTHER RESOLVED that APA re-affirms that APA (2015) encourages psychologists to:

- Acknowledge the diversity and complexity of identities and experiences and recognize transgender and gender nonbinary identities as healthy expressions of gender
- Recognize that descriptions of any gender identity or expression as unnatural, abhorrent, or unhealthy perpetuate stigma for sexual and gender minorities, and have negative mental health and social consequences
- Assist clients in a developmentally appropriate manner to explore and understand the cultural and familial influence on gender roles and expression. Psychologists are urged to help clients in a developmentally appropriate manner understand the societal contexts of sexism, heterosexism, transphobia, racism and other forms of social oppression, and to use a developmental multicultural- and gender-affirmative framework in research, teaching, training, and supervision;

BE IT FURTHER RESOLVED that the American Psychological Association opposes GICE because there is evidence of former participants reporting harm resulting from their experiences of GICE and the contribution that such efforts make to social stigma, injustice, and prejudice directed at gender diverse individuals, consistent with other major professional mental health associations, including the American Psychiatric Association (2018); American Counseling Association (2017), SAMHSA (2015), American Academy of Child & Adolescent Psychiatry (2018), World Health Organization (n.d.) and World Psychiatric Association (2016);

BE IT FURTHER RESOLVED that the APA, because of evidence of harm and lack of evidence of efficacy, supports public policies and legislation that prohibit, or aim to reduce GICE, cissexism, and anti-transgender and anti-gender nonbinary bias and that increase support for gender diversity;

BE IT FURTHER RESOLVED that the APA supports collaboration and partnerships with global, national and state and local partners to achieve the aims of this resolution;

BE IT FURTHER RESOLVED that the APA promotes professional training in gender-affirming practices and opposes professional training in GICE in any stage of the education of psychologists, including graduate training, continuing education, and professional development.

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TAB 176-7

APA Official Actions

Position Statement on Treatment of Transgender (Trans) and Gender Diverse Youth

Approved by the Board of Trustees, July 2020
Approved by the Assembly, April 2020

"Policy documents are approved by the APA Assembly and Board of Trustees. . . These are . . . position statements that define APA official policy on specific subjects. . ." – *APA Operations Manual*

Issue:

Transgender and gender non-conforming youth often experience an intensification of emotional distress when the physical changes of puberty occur in opposition to the adolescent's gender identity and sense of self. The onset of menses, for example, is unwanted and psychologically devastating for an adolescent transman (assigned female at birth). Worsening dysphoria may manifest as depression, anxiety, poor relationships with family and peers, self-harm and suicide. Racism, misogyny, economic disadvantage and neurodiversity can compound the risk of negative outcomes. Due to the dynamic nature of puberty development, lack of gender-affirming interventions (i.e. social, psychological, and medical) is not a neutral decision; youth often experience worsening dysphoria and negative impact on mental health as the incongruent and unwanted puberty progresses. Trans-affirming treatment, such as the use of puberty suppression, is associated with the relief of emotional distress, and notable gains in psychosocial and emotional development, in trans and gender diverse youth.

Gender-affirming treatment of trans and gender diverse youth who experience gender dysphoria due to the physical changes of puberty, may include suppression of puberty development with GnRH (gonadotropin releasing hormone) agonists, commonly referred to as "puberty blockers." Use of GnRH agonists, despite potential side effects (e.g., hot flashes, depression) can allow the adolescent a period of time, often several years, in which to further explore their gender identity and benefit from additional cognitive and emotional development. During this time, the youth and family can receive mental health and social support services, if needed, to navigate the gender affirmation process including the consideration of whether gender affirming hormone therapy is an appropriate next step. If during this discernment period further adolescent development leads to increased comfort with the birth-assigned gender, the GnRH agonist can be discontinued, and puberty allowed to resume. If the developmental trajectory affirms the trans identity, treatment with estrogen or testosterone can be instituted to facilitate development of affirmed secondary sex characteristics, if desired. Gender-affirming surgeries may follow in later adolescence or young adulthood. However, affirmation of gender identity is a highly individualized process. For gender diverse youth and their families, decisions to which gender-affirming medical, surgical, social, and/or legal procedures to pursue are best managed via an informed consent approach.

APA Position:

The American Psychiatric Association:

Pl. Trial Ex. 047

1. **Supports access to affirming and supportive treatment for trans and gender diverse youth and their families, including appropriate mental health services, and when indicated puberty suppression and medical transition support.**
2. **Opposes all legislative and other governmental attempts to limit access to these services for trans and gender diverse youth, or to sanction or criminalize the actions of physicians and other clinicians who provide them.**

TAB 176-8

APA Official Actions

Position Statement on Access to Care for Transgender and Gender Diverse Individuals

Approved by the Board of Trustees, July 2018
Approved by the Assembly, May 2018

"Policy documents are approved by the APA Assembly and Board of Trustees. . . . These are . . . position statements that define APA official policy on specific subjects. . ." – *APA Operations Manual*

Issue:
Significant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to assist gender diverse individuals seeking transition. However, private and public insurers often do not offer, or may specifically exclude, coverage for medically necessary treatments for gender transition. Access to medical care (both medical and surgical) positively impacts the mental health of transgender and gender diverse individuals.

The APA's vision statement includes the phrase: "Its vision is a society that has available, accessible, quality psychiatric diagnosis and treatment," yet currently, transgender and gender diverse individuals frequently lack available and accessible gender-affirming treatment. In addition, APA's values include the following points:

- best standards of clinical practice
- patient-focused treatment decisions
- scientifically-established principles of treatment
- advocacy for patients

Transgender and gender diverse individuals currently lack access to the best standards of clinical practice, do not have the opportunity to pursue patient-focused gender-affirming treatment decisions, and do not receive scientifically-established treatment. They could benefit significantly from APA's advocacy.

Position:

Therefore, the American Psychiatric Association:

1. **Recognizes that appropriately evaluated transgender and gender diverse individuals can benefit greatly from medical and surgical gender-affirming treatments.**
2. **Advocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment.**
3. **Opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.**
4. **Supports evidence-based coverage of all gender-affirming procedures which would help the**

Pl. Trial Ex. 048

mental well-being of gender diverse individuals

Authors:
Authors: Jack Drescher, M.D., Ellen Haller, M.D., APA Caucus of Lesbian, Gay and Bisexual Psychiatrists. Revised 2017 Eric Yarbrough, M.D., APA Caucus of LGBTQ Psychiatrists and the Council on Minority Mental Health and Health Disparities

TAB 176-9

ENDOCRINE SOCIETY
Hormone Science to Health

PES PEDIATRIC ENDOCRINE SOCIETY

TRANSGENDER HEALTH POSITION STATEMENT

INTRODUCTION

Over the last few decades, there has been a rapid expansion in the understanding of gender identity along with the implications for the care of transgender and gender diverse individuals. In parallel with the greater societal awareness of transgender individuals, evidence-based practices in caring for pediatric and adult transgender patients have been developed in response to scientific research. While there continue to be gaps in knowledge about the optimal care for transgender individuals, the framework for providing care is increasingly well-established as is the recognition of needed policy changes.

BACKGROUND

The medical consensus in the late 20th century was that transgender and gender incongruent individuals suffered a mental health disorder termed "gender identity disorder." Gender identity was considered malleable and subject to external influences. Today, however, this attitude is no longer considered valid. Considerable scientific evidence has emerged demonstrating a durable biological element underlying gender identity.[1,2] Individuals may make choices due to other factors in their lives, but there do not seem to be external forces that genuinely cause individuals to change gender identity.

Although the specific mechanisms guiding the biological underpinnings of gender identity are not entirely understood, there is evolving consensus that being transgender is not a mental health disorder. Such evidence stems from scientific studies suggesting that: 1) attempts to change gender identity in intersex patients to match external genitalia or chromosomes are typically unsuccessful[1,2]; 2) identical twins (who share the exact same genetic background) are more likely to both experience transgender identity as compared to fraternal (non-identical) twins[3]; 3) among individuals with female chromosomes (XX), rates of male gender identity are higher for those exposed to higher levels of androgens *in utero* relative to those without such exposure, and male (XY)-chromosome individuals with complete androgen insensitivity syndrome typically have female gender identity[4]; and 4) there are associations of certain brain scan or staining patterns with gender identity rather than external genitalia or chromosomes.[1,2]

CONSIDERATIONS

Transgender individuals are often denied insurance coverage for appropriate medical and psychological treatment. Those gender diverse youth who have barriers to accessing adequate healthcare have poorer overall physical and mental health compared to their cisgender peers.[5] Over the last decade, there has been considerable research on and development of evidence-based standards of care that have proven to be both safe and efficacious for the treatment of gender dysphoria/gender incongruence in youth and adults. There is also a growing understanding of the positive impact that increased access to such treatments can have on the mental health of these individuals.

The Endocrine Society's Clinical Practice Guideline on gender dysphoria/gender incongruence[6] provides the standard of care for supporting transgender individuals. The guideline establishes a methodical, conservative framework for gender-affirming care, including pubertal suppression, hormones and surgery and standardizes terminology to be used by healthcare professionals. These recommendations include evidence that treatment of gender dysphoria/incongruence is medically necessary and should be covered by insurance.

Despite increased awareness, many barriers to improving the health and well-being of transgender youth and adults remain. Oftentimes, medical treatment for gender dysphoria/gender incongruence is considered elective by insurance companies, which fail to provide coverage for physician-prescribed treatment. Access to appropriately trained healthcare professionals can also be challenging as there

[1]Saraswat A, Weinand JD, Safer JD. Evidence supporting the biologic nature of gender identity. *Endocr Pract.* Feb 2015;21(2):199-204. doi:10.4158/ep14351.ra

[2]Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab.* Dec 2014;99(12):4379-89. doi:10.1210/jc.2014-1919

[3]Heylens G, De Cuypere G, Zucker KJ, et al. Gender identity disorder in twins: a review of the case report literature. *J Sex Med.* Mar 2012;9(3):751-7. doi:10.1111/j.1743-6109.2011.02567.x

[4]Dessens AB, Slijper FM, Drop SL. Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. *Arch Sex Behav.* Aug 2005;34(4):389-97. doi:10.1007/s10508-005-4338-5

[5]Rider GN, McMorris BJ, Gower AL, Coleman E, Eisenberg ME. Health and Care Utilization of Transgender and Gender Nonconforming Youth: A Population-Based Study. *Pediatrics.* 2018;141(3):e20171683. doi:10.1542/peds.2017-1683

[6]Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* Nov 1 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

is a lack of formal education on gender dysphoria/gender incongruence among clinicians trained in the United States. A 2016 survey of endocrinologists, the physicians most likely to care for these patients, found that over 80% have never received training on care of transgender patients.[7]

This can have an adverse impact on patient outcomes, particularly in rural and underserved areas. In fact, studies have indicated that 70% of transgender individuals have experienced maltreatment by medical providers, including harassment and violence.[7] Many transgender individuals have been subjected to conversion therapy, or efforts to change a transgender person's gender identity using psychological interventions; this is known to be associated with adverse mental health outcomes, including suicidality, and is banned in 20 states and the District of Columbia.[8]

Transgender individuals who have been denied care show an increased likelihood of dying by suicide and engaging in self-harm.[7] Transgender/gender incongruent youth who had access to pubertal suppression, a treatment which is fully reversible and prevents development of secondary sex characteristics not in alignment with their gender identity, have lower lifetime odds of suicidal ideation compared to those youth who desired pubertal suppression but did not have access to such treatment.[9] Youth who are able to access gender-affirming care, including pubertal suppression, hormones and surgery based on conservative medical guidelines and consultation from medical and mental health experts, experience significantly improved mental health outcomes over time, similar to their cis-gender peers.[10-12] Pre-pubertal youth who are supported and affirmed in their social transitions long before medical interventions are indicated, experience no elevation in depression compared to their cis-gender peers.[12] It is critical that transgender individuals have access to the appropriate treatment and care to ensure their health and well-being.

FUTURE CONSIDERATIONS

While the data are strong for both a biological underpinning to gender identity and the relative safety of hormone treatment (when appropriately monitored medically), there are gaps in knowledge that are necessary to address in order to optimize care. Comparative effectiveness research in hormone regimens is needed to determine: the best endocrine and surgical protocols[13], as it is not yet known if certain regimens are safer or more effective than others; the degree of improvement as a result of the intervention (e.g. decrease in mental health diagnoses); the need for training of health care providers and the most effective training methods; and to build the body of evidence pertaining to cardiovascular, malignancy, or other long-term risks from hormone interventions, particularly as the transgender individual ages. Additional studies are needed to elucidate the biological processes underlying gender identity; such studies may lead to destigmatization and may also decrease health disparities for gender minorities. In addition, further studies are needed to determine strategies for fertility preservation and to investigate long-term outcomes of early medical intervention, including pubertal suppression, gender-affirming hormones and gender-affirming surgeries for transgender/gender incongruent youth. To successfully establish and enact these protocols requires long-term, large-scale studies across countries that employ similar care protocols.

POSITIONS

- There is a durable biological underpinning to gender identity that should be considered in policy determinations.
- Medical intervention for transgender youth and adults (including puberty suppression, hormone therapy and medically indicated surgery) is effective, relatively safe (when appropriately monitored), and has been established as the standard of care.[6] Federal and private insurers should cover such interventions as prescribed by a physician as well as the appropriate medical screenings that are recommended for all body tissues that a person may have.
- Increased funding for national pediatric and adult transgender health research programs is needed to close the gaps in knowledge regarding transgender medical care and should be made a priority.

[7]Davidge-Pitts C, Nippoldt TB, Danoff A, Radziejewski L, Natt N. Transgender Health in Endocrinology: Current Status of Endocrinology Fellowship Programs and Practicing Clinicians. *J Clin Endocrinol Metab*. Apr 1 2017;102(4):1286-1290. doi:10.1210/jc.2016-3007

[8]Turban JL, Beckwith N, Reisner SL, Keuroghlian AS. Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults. *JAMA Psychiatry*. Sep 11 2019;77(1):1-9. doi:10.1001/jamapsychiatry.2019.2285

[9]Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. Feb 2020;145(2)doi:10.1542/peds.2019-1725

[10]de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. Oct 2014;134(4):696-704. doi:10.1542/peds.2013-2958

[11]Kuper LE, Stewart S, Preston S, Lau M, Lopez X. Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy. *Pediatrics*. Apr 2020;145(4)doi:10.1542/peds.2019-3006

[12]Achille C, Taggart T, Eaton NR, et al. Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results. *Int J Pediatr Endocrinol*. 2020;2020:8. doi:10.1186/s13633-020-00078-2

[13]Safer JD, Tangpricha V. Care of the Transgender Patient. *Ann Intern Med*. Jul 2 2019;171(1):Itc1-Itc16. doi:10.7326/aitc201907020

No. 23-12155

In the United States Court of Appeals for the Eleventh Circuit

AUGUST DEKKER, BRIT ROTHSTEIN, SUSAN DOE, by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., by and through his parent and next friend, JADE LADUE,

Plaintiffs-Appellees,

v.

SECRETARY, FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, *et al.*,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Northern District of Florida, No. 4:22-cv-00325, Honorable Robert L. Hinkle, District Judge

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TAB 176-22

EPSDT - A Guide for States:
Coverage in the Medicaid Benefit for Children and Adolescents

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Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

JUNE 2014

Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html

Pl. Trial Ex. 062

PLAINTIFFS001533

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I. INTRODUCTION

The Medicaid program's benefit for children and adolescents is known as Early and Periodic Screening, Diagnostic and Treatment services, or EPSDT. EPSDT provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act (the Act). The EPSDT benefit is more robust than the Medicaid benefit for adults and is designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible. The goal of EPSDT is to assure that individual children get the health care they need when they need it – the right care to the right child at the right time in the right setting.

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States share responsibility for implementing the benefit, along with the Centers for Medicare & Medicaid Services (CMS). States have an affirmative obligation to make sure that Medicaid-eligible children and their families are aware of EPSDT and have access to required screenings and necessary treatment services.[1] States also have broad flexibility to determine how to best ensure such services are provided. In general, they either administer the benefit outright (through fee for service arrangements) or provide oversight to private entities with whom they have contracted to administer the benefit (e.g., managed care entities). States must arrange (directly or through delegations or contracts) for children to receive the physical, mental, vision, hearing, and dental services they need to treat health problems and conditions. Through the EPSDT benefit, children's health problems should be addressed before they become advanced and treatment is more difficult and costly.

[1] CMS, State Medicaid Manual §§ 5010, 5121, 5310 (requiring states to "[a]ssure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly,. . . that informing methods are effective, . . . [and] that services covered under Medicaid are available.")

EPSDT entitles enrolled infants, children and adolescents to any treatment or procedure that fits within any of the categories of Medicaid-covered services listed in Section 1905(a) of the Act if that treatment or service is necessary to "correct or ameliorate" defects and physical and mental illnesses or conditions.[2] This includes physician, nurse practitioner and hospital services; physical, speech/language, and occupational therapies; home health services, including medical equipment, supplies, and appliances; treatment for mental health and substance use disorders; treatment for vision, hearing and dental diseases and disorders, and much more. This broad coverage requirement results in a comprehensive, high-quality health benefit for children under age 21 enrolled in Medicaid.

Children's health problems should be addressed before they become advanced and treatment is more difficult and costly.

States report annually to CMS certain data about their delivery of services under the EPSDT benefit.[3] The reporting is made on the CMS Form 416. CMS and states use this data to monitor EPSDT performance.

This guide is intended to help states, health care providers and others to understand the scope of services that are covered under EPSDT so that they may realize EPSDT's goals and provide the best possible child and adolescent health benefit through their Medicaid programs. While it does not establish new EPSDT policy, this guide serves the important purpose of compiling into a single document various EPSDT policy guidances that CMS has issued over the years.

This guide outlines:

- ✓ EPSDT's screening requirements, including when interperiodic screening should be provided;
- ✓ Scope of services covered under EPSDT;
- ✓ EPSDT's requirements governing dental, vision, and hearing services;
- ✓ Permissible limitations on service coverage under EPSDT;

[2] Section 1905(r)(5) of the Social Security Act.
[3] Sections 1902(a)(43)(D) and 2108(e) of the Social Security Act; CMS, State Medicaid Manual § 2700.4.

- ✓ States' responsibilities to assure access to EPSDT services and providers;
- ✓ Assistance to states as they work with managed care plans to provide the best child health benefit possible; and
- ✓ Notice and appeal procedures required when services are denied, reduced or terminated.

II. PERIODIC AND INTERPERIODIC SCREENINGS

EPSDT covers regular screening services (check-ups) for infants, children and adolescents. These screenings are designed to identify health and developmental issues as early as possible. States have the responsibility to ensure that all eligible children (and their families) are informed of both the availability of screening services, and that a formal request for an EPSDT screening service is not required. States must provide or arrange for screening services both at established times and on an as-needed basis. Covered screening services are medical, mental health, vision, hearing and dental. Medical screenings has five components:

- ✓ Comprehensive health and developmental history that assesses for both physical and mental health, as well as for substance use disorders;4
- ✓ Comprehensive, unclothed physical examination;
- ✓ Appropriate immunizations, in accordance with the schedule for pediatric vaccines established by the Advisory Committee on Immunization Practices;
- ✓ Laboratory testing (including blood lead screening appropriate for age and risk factors);5 and
- ✓ Health education and anticipatory guidance for both the child and caregiver.6

Under the Act, states must establish a periodicity schedule for each type of screening service: medical, vision, hearing, and dental. The periodicity schedules set the frequency by which certain services should be provided and will be covered.[7] The schedules are not prescribed by federal law, but should be based on current standards of pediatric medical and dental practice, and states are required to consult with recognized medical and dental organizations involved in child health care to assist in developing their periodicity schedules. One commonly used source is Bright Futures (developed by the American Academy of Pediatrics), which, for example, suggests that developmental screenings be conducted when children are ages 9 months, 18 months, and 30 months. The American Academy of Pediatric Dentistry (AAPD) has published a recommended periodicity schedule for dental services for children and adolescents. States should review their EPSDT periodicity schedules regularly to keep them up to date.

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[4] CMS issued an Informational Bulletin on March 27, 2013, discussing Prevention and Early Identification of Mental Health and Substance Use Conditions in Children and informing states about resources available to help them meet the needs of children under EPSDT.
[5] CMS issued guidance on June 22, 2012 to align blood lead screening for Medicaid children with recommendations of the Centers for Disease Control and Prevention (CDC). After providing data that demonstrates that universal screening is not the most effective approach to identifying childhood exposure to lead, a state may request to implement a targeted lead screening plan rather than continue universal screening of all Medicaid-eligible children ages 1 and 2.
[6] Section 1905(r)(1)(B) of the Social Security Act.
[7] 42 C.F.R. § 441.58; CMS, State Medicaid Manual §§ 5110, 5140.

States should review their EPSDT periodicity schedules regularly to keep them up to date.

EPSDT also requires coverage of medically necessary "interperiodic" screening outside of the state's periodicity schedule. Coverage for such screenings is required based on an indication of a medical need to diagnose an illness or condition that was not present at the regularly scheduled screening or to determine if there has been a change in a previously diagnosed illness or condition that requires additional services. The determination of whether a screening service outside of the periodicity schedule is necessary may be made by the child's physician or dentist, or by a health, developmental, or educational professional who comes into contact with a child outside of the formal health care system. This includes, for example, personnel working for state early intervention or special education programs, Head Start, and the Special Supplemental Nutrition Program for Women, Infants, and Children. A state may not limit the number of medically necessary screenings a child receives and may not require prior authorization for either periodic or "interperiodic" screenings.

Example of Screenings Beyond Those Required by the Periodicity Schedule
A child receives a regularly scheduled periodic vision screening at age 5 at which no problem is detected. According to the state's periodicity schedule, his next vision screening is due at age 7. At age 6, the school nurse recommends to the child's parent that the child see an optometrist because a teacher suspects a vision problem. Even though the next scheduled vision screening is not due until the age of 7, the child would be entitled to receive a timely "interperiodic" screening to determine if there is a vision problem for which treatment is needed. The screening should not be delayed if there is a concern the child may have a vision problem. Source: NPRM, 58 Fed. Reg. 51288, 51290, 51291 (Oct. 1, 1993)

Screening services provide the crucial link to necessary covered treatment, as EPSDT requires states to "arrang[e] for . . . corrective treatment," either directly or through referral to appropriate providers or licensed practitioners, for any illness or condition detected by a screening.[8] The affirmative obligation to connect children with necessary treatment makes EPSDT different from Medicaid for adults.[9] It is a crucial component of a quality child health benefit.

[8] Section 1902(a)(43)(C) of the Social Security Act.
[9] CMS, State Medicaid Manual § 5124.B.

The affirmative obligation to connect children with necessary treatment makes EPSDT different from Medicaid for adults.

Any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a screening service. The screening *need not be* conducted by a Medicaid provider in order to trigger EPSDT coverage for follow up diagnostic services and medically necessary treatment by a qualified Medicaid provider. A screening service provided before a child enrolls in Medicaid is sufficient to trigger EPSDT coverage, after enrollment, for follow-up diagnostic services and necessary treatment. The family or beneficiary need not formally request an EPSDT screening in order to receive the benefits of EPSDT. Rather, any visit or contact with a qualified medical professional is sufficient to satisfy EPSDT's screening requirement, and states should consider a beneficiary who is receiving services to be participating in EPSDT, whether the beneficiary requested screening services directly from the state or the health care provider.[10]

Any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a screening service.

States establish their own fee schedules for screening services and should be using Health Insurance Portability and Accountability Act (HIPAA) compliant billing codes. States may develop a bundled payment rate to pay for the physical health screening components under one billing code. States may also recognize each component of the EPSDT screening separately. For example, one state pays for the visit itself with one code and pays separately for each individual screening service delivered during the visit. This payment methodology not only encourages providers to perform every component of an EPSDT well-child visit, it also provides the state, through claims, information as to whether the physician actually met the elements of the EPSDT guidelines set out in the periodicity

[10] CMS, State Medicaid Manual § 5310; HCFA, Title XIX State Agency Letter No. 91-33 (April 3, 1991).

schedules. States may encourage providers to perform all five components of the EPSDT screening but may not exclude providers who perform only partial screenings from being reimbursed for the parts they do provide.

Professional guidelines (e.g., Bright Futures) recommend that physicians include an oral health screening as part of the well-child visit at specified ages. In addition, states are permitted to include dental or oral health screening as a separately covered EPSDT service. These screening services, which may be performed by dental professionals or by medical professionals according to state scope of practice rules, can take place in community or group settings as well as in clinics or medical and dental offices. Such screenings can be helpful in identifying children with unmet dental care needs so they can be referred to a dental professional for treatment. Two new procedure codes were added to the Code on Dental Procedures and Nomenclature (CDT) in 2012 to facilitate payment for oral health screenings and assessments: CDT 0190 and CDT 0191.

In 2012, two new procedure codes were added to facilitate payment for oral health screenings and assessments: CDT 0190 and 0191.

Vision and hearing screening services must also be provided. States should consult with ophthalmologists and optometrists to determine what procedures should be used during a vision screening and to establish the criteria for referral for a diagnostic examination. For hearing screenings, appropriate procedures for screening and methods of administering them can be obtained from audiologists or from state health or education departments.[11]

[11] CMS, State Medicaid Manual § 5123.2.F.

III. DIAGNOSTIC SERVICES

EPSDT covers medically necessary diagnostic services. When a screening examination indicates the need for further evaluation of a child's health, the child should be appropriately referred for diagnosis without delay.

A child's diagnosis may be performed by a physician, dentist or other practitioner qualified to evaluate and diagnose health problems at locations, including practitioners' offices, maternal and child health (MCH) facilities, community health centers, rehabilitation centers, and hospital outpatient departments. Diagnosis can generally be made on an outpatient basis. However, inpatient services are covered when necessary to complete a diagnosis.

When a screening examination indicates the need for further evaluation of a child's health, the child should be referred for diagnosis without delay.

IV. THE SCOPE OF EPSDT TREATMENT SERVICES

A. Scope of Services

The Act provides for coverage of all medically necessary services that are included within the categories of mandatory and optional services listed in section 1905(a), regardless of whether such services are covered under the State Plan. These include physician and hospital services, private duty nursing, personal care services, home health and medical equipment and supplies, rehabilitative services, and vision, hearing, and dental services. Covered EPSDT services also include "any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary."[12] The role of states is to make sure the full range of EPSDT services is available as well as to assure that families of enrolled children are aware of and have access to those services so as to meet the individual child's needs. The broad scope of services enables states to design a child health benefit to meet the individual needs of the children served by its Medicaid program—a benefit design that has the potential to result in better care and healthier children at a lower overall cost. As discussed in the next section: while children enrolled in Medicaid are entitled to a broad scope of treatment services, no such service is covered under Medicaid unless medically necessary for that particular child.

The Act provides for coverage of all medically necessary services that are included within the categories of mandatory and optional services listed in section 1905(a), regardless of whether such services are covered under the State Plan.

[12] Section 1905(a)(29) of the Social Security Act.

If a service, supply or equipment that has been determined to be medically necessary for a child is not listed as covered (for adults) in a State Medicaid Plan, the state will nonetheless need to provide it to the child as long as the service or supply could be covered under the State Plan, that is, as long as it is included within the categories of mandatory and optional services listed in section 1905(a). In such circumstances, the state would need to develop a payment methodology for the service, supply or equipment, including the possibility that payment may need to be made using a single-service agreement with an in-state provider or an out-of-state provider who will accept Medicaid payment.

A service need not cure a condition in order to be covered under EPSDT. Services that maintain or improve the child's current health condition are also covered in EPSDT because they "ameliorate" a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of "ameliorate" is to "make more tolerable." Thus, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose. This is particularly important for children with disabilities, because such services can prevent conditions from worsening, reduce pain, and avert the development of more costly illnesses and conditions. Other, less common examples include items of durable medical equipment, such as decubitus cushions, bed rails and augmentative communication devices. Such services are a crucial component of a good, comprehensive child-focused health benefit.

B. Covering a Range of Treatment Services to Meet a Child's Needs

As noted above, EPSDT covers physical and mental health and substance use disorder services, regardless of whether these services are provided under the State Plan and regardless of any restrictions that states may impose on coverage for adult services, as long as those services *could* be covered under the State Plan. This section provides some examples of EPSDT's broad scope of services, focusing on mental health and substance use services, personal care services, oral health and dental services, and vision and hearing services.

a. Mental Health and Substance Use Services

Treatment for mental health and substance use issues and conditions is available under a number of Medicaid service categories, including hospital and clinic services, physician services, and services provided by a licensed professional such as a psychologist. States should also make use of rehabilitative services. While rehabilitative services can meet a range of children's treatment needs, they

can be particularly critical for children with mental health and substance use issues. Rehabilitative services are defined to include:

> *any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level.*[13]

Like other services covered under EPSDT, rehabilitative services need not actually cure a disability or completely restore an individual to a previous functional level. Rather, such services are covered when they ameliorate a physical or mental disability, as discussed above. Moreover, determinations of whether a service is rehabilitative must take into consideration that a child may not have attained the ability to perform certain functions. That is, a child's rehabilitative services plan of care should reflect goals appropriate for the child's developmental stage.

Rehabilitative services are particularly critical for children with mental health and substance use issues.

Depending on the interventions that the individual child needs, services that can be covered as rehabilitative services include:

- ✓ Community-based crisis services, such as mobile crisis teams, and intensive outpatient services;
- ✓ Individualized mental health and substance use treatment services, including in non-traditional settings such as a school, a workplace or at home;
- ✓ Medication management;
- ✓ Counseling and therapy, including to eliminate psychological barriers that would impede development of community living skills; and
- ✓ Rehabilitative equipment, for instance daily living aids.

With respect to the provision of rehabilitative services, including those noted above, CMS requires more specificity of providers and services due to the wide spectrum of rehabilitative services coverable under the broad definition. CMS

[13] Section 1905(a)(13) of the Social Security Act; 42 C.F.R. § 440.130(d).

would expect a state to include in their State Plan the services, and providers with their qualifications, as well as a reimbursement methodology for each service it provides. CMS is available to provide technical assistance to states that are covering a service for children that has not otherwise been identified in their State Plan.

A number of home and community-based services, including those that can be provided through EPSDT, have proven to significantly enhance positive outcomes for children and youth. These include intensive care coordination ("wraparound"), intensive in-home services, and mobile crisis response and stabilization.

CMS has issued detailed guidance encouraging states to include screening, assessments, and treatments focusing on children who have been victims of complex trauma. EPSDT can be a crucial tool in addressing the profound needs of this population, including children who are involved in the child welfare system.

b. Personal Care Services

EPSDT requires coverage of medically necessary personal care services, which:

> *are furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility . . . or institution for mental disease, that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State), otherwise authorized for the individual in accordance with a service plan approved by the State; (B) provided by an individual who is qualified to provide such services and is not a member of the individual's family; and (C) furnished in a home or . . . in other location.*[14]

Personal care services provide a range of assistance with performing activities of daily living, such as dressing, eating, bathing, transferring, and toileting; and instrumental activities of daily living, such as preparing meals and managing medications.[15] While it is optional for states to provide personal care services for adults in locations other than the home, this is not the case for a child. Under EPSDT, personal care services are to be provided, for example, in a school or group home if necessary to "correct or ameliorate" a condition.

The determination of whether a child needs personal care services must be based upon the child's individual needs and provided in accordance with a plan of treatment or service plan. Under regular State Plan Medicaid, no Medicaid payments are available for personal care services provided by the child's legally

[14] Section 1905(a)(24) of the Social Security Act; 42 C.F.R. § 440.167.
[15] CMS, State Medicaid Manual § 4480.

responsible relatives.[16] In addition, the determination of whether a child needs personal care services must be based upon the child's individual needs and a consideration of family resources that are actually—not hypothetically—available.

c. Oral Health and Dental Services

Dental services required in the EPSDT benefit include:[17]

- ✓ Dental care needed for relief of pain, infection, restoration of teeth, and maintenance of dental health (provided at as early an age as necessary); and
- ✓ Emergency, preventive, and therapeutic services for dental disease that, if left untreated, may become acute dental problems or cause irreversible damage to the teeth or supporting structures.18

In addition, medically necessary oral health and dental services,[19] including those identified during an oral screening or a dental exam, are covered for children. States must provide orthodontic services to EPSDT-eligible children to the extent necessary to prevent disease and promote oral health, and restore oral structures to health and function.[20] Orthodontic services for cosmetic purposes are not covered.

Once a child reaches the age specified by the state in its pediatric dental periodicity schedule, typically age one, a direct dental referral is required.[21] The referral must be for an encounter with a dentist or with another dental professional, such as a dental hygienist, working under the supervision of a dentist.[22] Dental supervision includes the entire range, for example, direct, indirect, general, public health and collaborative practice arrangements.

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[16] 42 C.F.R. § 440.167.

[17] Information on CMS efforts working with states to improve access to oral health services for children enrolled in Medicaid and CHIP can be found in CMS, *Improving Access to and Utilization of Oral Health Services for Children in Medicaid and CHIP Programs: CMS Oral Health Strategy* (April 11, 2011). Approaches states can use to improve the delivery of dental and oral health services to children in Medicaid and CHIP can be found in *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children and Adolescents* and in *Improving Oral Health Care Delivery in Medicaid and CHIP: A Toolkit for States*. All of these documents are available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Dental-Care.html.

[18] CMS, State Medicaid Manual § 5124.B.2.b.

[19] CMS, State Medicaid Manual § 2700.4 (Form 416 Instructions, Note for Line 12 Data). Dental services are those performed by or under the supervision of a dentist. Oral health services are those performed by other licensed providers not working under the supervision of a dentist, for example, a physician or nurse, or by a dental professional operating without a supervisory relationship to a dentist (e.g., an independent practice dental hygienist).

[20] CMS, State Medicaid Manual § 5124.B.2.b

[21] 42 C.F.R. § 441.56(b)(vi).

[22] CMS, State Medicaid Manual § 5123.2.G.

Current clinical guidelines recommend that a child have a first dental visit when the first tooth erupts or by age one.

Dental care must be provided at intervals indicated in the pediatric dental periodicity schedule adopted by the state after consultation with a recognized dental organization involved in child health care.[23] Current clinical guidelines recommend that a child have a first dental visit when the first tooth erupts or by age one, whichever occurs first. Dental care that is deemed medically necessary for an individual child is covered even when the frequency is greater than specified in the periodicity schedule.[24] For example, a child determined by a qualified provider to be at moderate or high risk for developing early childhood caries could be covered to receive dental exams and preventive treatments more frequently than the twice-yearly periodicity schedule recommended by the AAPD.

As determined by dental practice acts in individual states, there is a wide range of dental professionals who can work under the supervision of a dentist, for example, dental hygienists, dental therapists, dental health aide therapists, dental hygienists in advanced practice, advanced practice dental therapists, dental assistants, and community dental health coordinators. Some state practice acts permit specified dental professionals to work without dentist supervision in certain circumstances. Such provisions can help ensure access to dental care as well as promote an integrated health care delivery system. As with medical care, any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a dental or oral health service to a Medicaid enrollee. To qualify for federal matching funds, State Plans must list all provider types that will be permitted to bill for dental or oral health services. However, rendering providers (providers who actually serve the patient) need not be separately enumerated in the State Plan.

Better integration of primary medical care with dental care can help identify children at risk for tooth decay at the youngest age possible, offer evidence-based preventive care, such as fluoride varnish and oral health education, and refer children to a dental professional for a complete check-up and any needed treatment. Three oral health risk assessment CDT billing codes can support this

[23] Section 1905(r)(3) of the Social Security Act; CMS, State Medicaid Manual § 5110.
[24] CMS, State Medicaid Manual § 5110.

approach, potentially preventing the need for costly treatment, such as that provided in an operating room.

State Medicaid and CHIP programs can use risk assessment codes to help children access services based on their individual levels of risk, instead of assuming that all children need the same level of intervention. AAPD guidelines encourage providers to customize care plans based on an assessment of each child's individual risk for developing dental disease. Risk assessment resources are available for providers, including an assessment tool from AAPD that includes a caries-risk assessment form, clinical guidelines and treatment protocols.

In addition to dental providers, states may reimburse primary care medical providers for conducting oral health risk assessments, providing oral health education to parents and children, applying preventive measures such as fluoride varnish, and making referrals to dental professionals. The CMCS oral health strategy guide, *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children & Adolescents*, provides additional information on oral health and EPSDT.

d. Vision and Hearing Services

Vision and hearing services are an essential component of the EPSDT benefit. Hearing impairments can lead to other problems, including interference with normal language development in young children. They can also delay a child's social, emotional, and academic development. Vision problems can be evidence of serious, degenerative conditions, and can also lead to delays in learning and social development.

EPSDT requires that vision and hearing services be provided at intervals that meet reasonable standards as determined in consultation with medical experts, and at other intervals, as medically necessary, to determine the existence of a suspected illness or condition. At a minimum, vision services must include diagnosis and treatment for defects in vision, including eyeglasses. Glasses to replace those that are lost, broken, or stolen also must be covered. Hearing services must include, at a minimum, diagnosis and treatment for defects in hearing, including hearing aids.[25]

In addition, if hearing and vision problems are detected through screening, medically necessary services that are coverable under section 1905(a) must be covered. This includes not only physician and clinic services, but services from licensed professionals such as ophthalmologists, and equipment such as augmentative communication devices and cochlear implants.

[25] Sections 1905(r)(2) and (4) of the Social Security Act.

e. *Other Services*

Examples of other services covered for children under Medicaid when medically necessary (and for which a federal match is available) include, but are not limited to, case management services (including targeted case management);[26] incontinence supplies; organ transplants and any related services; a specially adapted car seat that is needed by a child because of a medical problem or condition; and nutritional supplements.

Physicians and other providers use medical terminology, not Medicaid terms or legal terms, when recommending or prescribing medical services and treatments. If a requested service or treatment is not listed by name in Medicaid's list of services, it should nonetheless be provided if the service or item is determined to be medically necessary and coverable under the list of services at section 1905(a). In general, states are encouraged to include in their State Plans a range of provider types and settings likely to be sufficient to meet the needs of enrollees. Nonetheless, there may be cases in which the type of provider that is needed is not already participating in Medicaid. In such an instance, the state could meet the EPSDT requirement by, for example, entering into a single-service agreement with the needed provider.

When providers use medical terminology instead of Medicaid or legal terms to recommend medically necessary services, the recommended services should be covered if coverable under section 1905(a).

C. Enabling Services

a. *Transportation Services*

In order to promote access to needed preventive, diagnostic and treatment services, states must offer appointment scheduling assistance and are required to assure necessary transportation, to and from medical appointments, for children

[26] Section 1905(a)(19) of the Social Security Act; 42 C.F.R. §§ 440.169, 441.18.

enrolled in Medicaid.[27] This includes covering the costs of an ambulance, taxi, bus, or other carrier. It can also include reimbursing for mileage. As with other services covered through EPSDT, states may cover the least expensive means of transportation if it is actually available, accessible, and appropriate. For example, public transportation can be covered instead of a taxi if the public transportation is physically accessible for a particular beneficiary and takes a reasonable amount of time. In addition, "related travel expenses" are covered if medically necessary, including meals and lodging for a child and necessary attendant.[28]

Some states have addressed the transportation requirement by offering non-emergency transportation through brokers who coordinate transportation services, or through administrative managers who act as gatekeepers for transportation services. Transportation may also be included in managed care contracts. If a state chooses not to include transportation services in their managed care contracts, or otherwise to contract out administration of the service, the state must administer the service itself. No matter the type of arrangement, it is important to remember that the state has ultimate responsibility for ensuring the provision of transportation services.

b. Language Access and Culturally Appropriate Services

Many Medicaid-enrolled children live in families where English is not spoken at home. State Medicaid agencies and their contractors should inform eligible individuals about the EPSDT benefit with a combination of written and oral methods "using clear and nontechnical language" and "effectively informing those individuals who . . . cannot read or understand the English language."[29] State Medicaid agencies and Medicaid managed care plans, as recipients of federal funds, also have responsibilities to assure that covered services are delivered to children without a language barrier. They are required take "reasonable steps" to assure that individuals who are limited English proficient have meaningful access to Medicaid services.[30] This may include providing interpreter services, including at medical appointments, depending on factors such as the number of limited English proficient individuals served by the program.[31]

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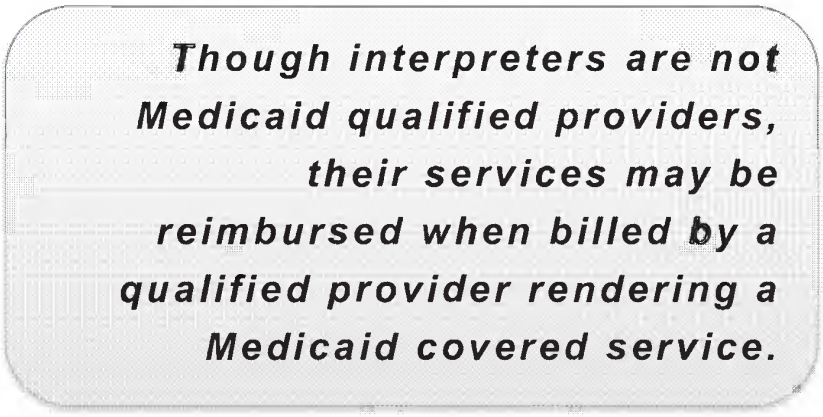
[27] Section 1905(a)(29) of the Social Security Act; 42 C.F.R. §§ 440.170, 441.62.
[28] 42 C.F.R. § 440.170(a).
[29] 42 C.F.R. § 441.56(a); CMS, State Medicaid Manual §§ 5121.A, 5121.C.
[30] 42 U.S.C. § 2000d (Title VI of the Civil Rights Act); Affordable Care Act § 1557; CMS Dear State Medicaid Director (Aug. 31, 2000).
[31] Department of Health & Human Services, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (August 8, 2003).

Though interpreter services are not classified as mandatory 1905(a) services, all providers who receive federal funds from HHS for the provision of Medicaid services are obligated, under Title VI of the Civil Rights Act, to make language services available to those with limited English proficiency.



States are not required to (but may) reimburse providers for the cost of language services. States may consider the cost of language services to be included in the regular rate of reimbursement for the underlying direct service. In those cases, Medicaid providers are obligated to provide language services to those with limited English proficiency and to bear the costs for doing so. Alternatively, states may allow providers to bill specifically for interpreter services. States have the option to claim for the cost of interpretation services, either as medical-assistance related expenditures or as administration.[32]

Claiming Federal Matching Funds for Interpreter Services. Interpreters are not Medicaid qualified providers. However, their services may be reimbursed when billed by a qualified provider rendering a Medicaid covered service. Interpreters may not be paid separately. As of February 2009, oral interpreter services can be claimed using billing code T-1013 along with the CPT code used for the medical encounter. States can also raise reimbursement rates to recognize additional service costs, including interpreter costs, but must do so for services rendered by all providers in the class. With the enactment of the Children's Health Insurance Program Reauthorization Act in 2009, states were given the option to claim a higher federal matching rate (75% under Medicaid) for translation and interpretation services that are claimed as administration and are related to the enrollment, retention and use of services under Medicaid and CHIP by children of families for whom English is not their primary language.[33] Otherwise, longstanding CMS policy permits reimbursement at the standard 50% federal

[32] CMS, Dear State Medicaid Director (July 1, 2010); CMS, CMCS Informational Bulletin: *Recent Developments in Medicaid* (April 26, 2011).
[33] Section 1903(a)(2)(E) of the Social Security Act.

matching rate for translation and interpretation activities that are claimed as an administrative expense, so long as they are not included and paid for as part of the reimbursement rate for direct services.[34]

The HHS Office for Civil Rights and the Department of Justice have provided guidance for recipients of federal funds on expectations of how to provide language services.[35]

State Medicaid programs, managed care entities, and Medicaid-participating health care providers should all be culturally competent. This means they need to recognize and understand the cultural beliefs and health practices of the families and children they serve, and use that knowledge to implement policies and inform practices that support quality interventions and good health outcomes for children. Given changing demographics, this process is ongoing. The DHHS Office of Minority Health offers numerous resources, including:

- ✓ Center for Linguistic and Cultural Competence in Health Care;
- ✓ Think Cultural Health;
- ✓ A Physician's Practical Guide to Culturally Competent Care;
- ✓ The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards); and
- ✓ The National CLAS Standards' implementation guide, A Blueprint for Advancing and Sustaining CLAS Policy and Practice.

D. Settings and Locations for Services

a. Services Provided Out of State

States may need to rely upon out-of-state services if necessary covered services are not available locally, or if a Medicaid beneficiary is out of state at the time a need for medical services arises. States are required to pay for services provided

[34] CMS, Dear State Medicaid Director (August 31, 2000).
[35] *Id*; U.S. Department of Justice, Executive Order 13166.

in another state to the same extent services furnished in-state would be paid for if:

- ✓ The out-of-state services are required because of an emergency;
- ✓ The child's health would be endangered if she or he were required to travel to their home state;
- ✓ The state determines that the needed services are more readily available in the other state; or
- ✓ It is a general practice of the locality to use the services of an out-of-state provider, for example, in areas that border another state.[36]

Including out-of-state providers gives states the opportunity to expand the range and accessibility of Medicaid services that are available to their enrollees.[37]

b. Services Provided in Schools

Services provided in schools can play an important role in the health care of adolescents and children. Whether implemented for children with special needs under the Individuals with Disabilities Education Act (IDEA) or through school-based or linked health clinics, school-centered programs may be able to provide medical and dental care efficiently and effectively while avoiding extended absences from school.

In order for Medicaid to reimburse for health services provided in the schools, the services must be included among those listed in section 1905(a) of the Act and included in the State Plan, or be available under the EPSDT benefit. There is no benefit category in the Medicaid statute titled "school health services" or "early intervention services." Therefore a state must describe its school health services in terms of the specific section 1905(a) services which will be provided. In addition, there must be a provider agreement in place between the state Medicaid agency and the provider billing for the service; and the school must agree to comply with Medicaid-specific requirements regarding service documentation and claims submission.[38] States are encouraged to promote relationships between school-based providers and managed care plans.

Services provided in schools can play an important role in the health care of adolescents and children.

[36] Section 1902(a)(16) of the Social Security Act; 42 C.F.R. § 431.52.
[37] HCFA, Dear State Medicaid Director (July 25, 2000).
[38] 42 C.F.R. § 431.107.

Schools are particularly appropriate places to provide medical, vision, and hearing screenings; vaccinations; some dental care; and behavioral health services. The Individuals with Disabilities Education Act (IDEA) requires that every child with a disability have available a free appropriate public education that includes special education and related services. Part B of IDEA requires the development and implementation of an individualized education program (IEP) that addresses the unique needs of each child with a disability ages 3 through 21.[39] A child's IEP identifies the special education and related services needed by that child. Medicaid covered services included in the IEP may be provided in, and reimbursed to, schools. Part C of IDEA covers early intervention services, which are developmental services designed to meet a child's developmental needs in physical, cognitive, communication, adaptive, and social and emotional development, for children from birth to age 3. These services are provided pursuant to an Individualized Family Service Plan (IFSP).

Examples of IDEA services that can be covered by Medicaid for a Medicaid eligible child include physical therapy, occupational therapy, personal care, and services for children with speech, hearing and language disorders.[40]

c. Most Integrated Setting Appropriate

Title II of the Americans with Disabilities Act (ADA) prohibits discrimination on the basis of disability in public programs, including Medicaid. In *Olmstead v. L.C.,* the Supreme Court held that unjustified institutionalization of Medicaid beneficiaries violates the ADA. Accordingly, states must cover services in the community, rather than in an institution, when the need for community services can be reasonably accommodated and providing services in the community will not fundamentally alter the state's Medicaid program.

Community-based care is a best practice for supporting children with disabilities and chronic conditions.

CMS has long encouraged states to provide services in home and community settings, particularly for children, not only because of *Olmstead,* but because community-based care is considered a best practice for supporting children with

[39] While EPSDT covers children only through age 20 (up to the 21st birthday), the IDEA covers children through age 21 (up to the 22nd birthday).
[40] Additional information about Medicaid-covered services provided in schools can be found in the CMS, *Medicaid School Based Administrative Claiming Guide* (2003).

disabilities and chronic conditions. In addition, it is generally more cost-effective.[41]

EPSDT provides states with many options for covering physical and mental health services in the community. The EPSDT benefit requires coverage of medically necessary personal care, private duty nursing, physical, occupational and speech-language therapy. And, as discussed below, optional services provided through home and community based services waivers can further advance the state's efforts to provide services in the community.

[41] HCFA, Dear State Medicaid Director, Olmstead Update Nos. 2 and 3 (July 25, 2000), No. 5 (January 10, 2001); CMS, Dear State Medicaid Director (May 20, 2010); CMS, Joint CMCS and SAMHSA Informational Bulletin: *Coverage of Behavioral Health Services for Children, Youth, and Young Adults with Significant Mental Health Conditions* (May 7, 2013).

V. PERMISSIBLE LIMITATIONS ON COVERAGE OF EPSDT SERVICES

A. Individual Medical Necessity

Services that fit within the scope of coverage under EPSDT must be provided to a child only if necessary to correct or ameliorate the individual child's physical or mental condition, i.e., only if "medically necessary." The determination of whether a service is medically necessary for an individual child must be made on a case-by-case basis, taking into account the particular needs of the child. The state (or the managed care entity as delegated by the state) should consider the child's long-term needs, not just what is required to address the immediate situation. The state should also consider all aspects of a child's needs, including nutritional, social development, and mental health and substance use disorders. States are permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases, but those parameters may not contradict or be more restrictive than the federal statutory requirement. As discussed above, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose.

Determination of whether a service is medically necessary must be made on a case-by-case basis, taking into account a particular child's needs.

Because medical necessity decisions are individualized, flat limits or hard limits based on a monetary cap or budgetary constraints are not consistent with EPSDT requirements.[42] States may adopt a definition of medical necessity that places tentative limits on services pending an individualized determination by the state, or that limits a treating provider's discretion, as a utilization control, but additional services must be provided if determined to be medically necessary for

[42] HCFA, *Regional Transmittal Notice* (Region IV) (Sept. 18, 1990); Memorandum from Rozann Abato, Acting Director, HCFA, to Associate Regional Administrator, Atlanta (Sept. 5, 1990); Memorandum from Christine Nye, HCFA Medicaid Director, to Regional Administrator Region VIII (FME-42) (1991).

an individual child.[43] For example, while a state may place in its State Plan a limit of a certain number of physical therapy visits per year for individuals age 21 and older, such a "hard" limit could not be applied to children. A state could impose a "soft" limit of a certain number of physical therapy visits annually for children, but if it were to be determined in an individual child's case, upon review, that additional physical therapy services were medically necessary to correct or ameliorate a diagnosed condition, those services would have to be covered.

While the treating health care provider has a responsibility for determining or recommending that a particular covered service is needed to correct or ameliorate the child's condition,[44] both the state and a child's treating provider play a role in determining whether a service is medically necessary. If there is a disagreement between the treating provider and the state's expert as to whether a service is medically necessary for a particular child, the state is responsible for making a decision, for the individual child, based on the evidence. That decision may be appealed by the child (or the child's family) under the state's Medicaid fair hearing procedures, as described in Section VIII below.

B. Prior Authorization

States may impose utilization controls to safeguard against unnecessary use of care and services. For example, a state may establish tentative limits on the amount of a treatment service a child can receive and require prior authorization for coverage of medically necessary services above those limits.[45] Prior authorization must be conducted on a case-by-case basis, evaluating each child's needs individually. Importantly, prior authorization procedures may not delay delivery of needed treatment services and must be consistent with the "preventive thrust" of EPSDT.[46] As such, prior authorization may not be required for any EPSDT screening services. In addition, medical management techniques used for mental health and substance use disorders should comply with the Mental Health Parity and Addiction Equity Act.

C. Experimental Treatments

EPSDT does not require coverage of treatments, services, or items that are experimental or investigational. Such services and items may, however, be covered at the state's discretion if it is determined that the treatment or item would be effective to address the child's condition.[47] Neither the Federal Medicaid statute nor the regulations define what constitutes an experimental

[43] 42 C.F.R. §§ 440.230(c), (d); HCFA Dear State Medicaid Director (May 26, 1993).
[44] Sections 1905(a) and (r) of the Social Security Act.
[45] *Id.*
[46] H.R. Rep. No. 101-247 at 399, *reprinted in* U.S.C.C.A.N. 1906, 2125.
[47] CMS, State Medicaid Manual §§ 4385.C.1, 5122.F.

treatment. The state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available.[48]

Medicare guidance on whether a service is experimental or investigational is not determinative of the issue and may not be relevant to the pediatric population.[49]

D. Cost-Effective Alternatives

A state may not deny medically necessary treatment to a child based on cost alone, but may consider the relative cost effectiveness of alternatives as part of the prior authorization process. Also, a state need not make services available in every possible setting as long as the services are reasonably available through the settings where the service is actually offered. States may cover services in the most cost effective mode as long as the less expensive service is equally effective and actually available.[50] The child's quality of life must also be considered.[51] In addition, the ADA and the *Olmstead* decision require states to provide services in the most integrated setting appropriate to a child's needs, as long as doing so does not fundamentally alter the state's program. See above, Section IV.D. Thus, if an institutional setting is less costly than providing services in a home or community, the ADA's integration mandate may nevertheless require that the services be provided in the community.[52]

A state may not deny medically necessary treatment based on cost alone, but may consider the relative cost effectiveness of alternatives as part of the prior authorization process.

[48] Memorandum from S. Richardson to State Medicaid Directors (April 17, 1995).
[49] Memorandum from S. Richardson to State Medicaid Directors (April 17, 1995).
[50] CMS, Dear State Medicaid Director, Olmstead Update No. 4 (January 10, 2001); Letter from Rozann Abato, Acting Director, Medicaid Bureau, to State Medicaid Directors (May 26, 1993).
[51] *Id.*
[52] 28 C.F.R. § 35.130(d); CMS, Dear State Medicaid Director, Olmstead Update No. 4 (January 10, 2001); DOJ, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the ADA and *Olmstead v. L.C.* (June 22, 2011).

VI. SERVICES AVAILABLE UNDER OTHER FEDERAL AUTHORITIES

A. Home and Community Based Services Waivers

A state Medicaid program may offer services through home and community based services (HCBS) waiver programs. Such programs allow states to provide HCBS to individuals who would otherwise need long-term care in a nursing facility, intermediate care facility, or hospital. Waiver programs provide for coverage of services that are not otherwise available through the Medicaid program (including EPSDT) because they do not fit into one of the categories listed in section 1905(a). This includes habilitative services, respite services, or other services approved by CMS that can help prevent institutionalization. These programs are sometimes called 1915(c) waivers after the section of the Social Security Act that authorizes them.[53]

Children under age 21 who are enrolled in an HCBS waiver program are also entitled to all EPSDT screening, diagnostic, and treatment services. Because HCBS waivers can provide services not otherwise covered under Medicaid, waivers and EPSDT can be used together to provide a comprehensive benefit for children with disabilities who would otherwise need the level of care provided in an institutional setting. This enables those children to remain in their homes and communities while receiving medically necessary services and supports. The HCBS waiver services essentially "wrap-around" the EPSDT benefit. If a child enrolled in Medicaid is on a waiting list for HCBS waiver services, EPSDT requirements apply and necessary services that fit into the categories listed in 1905(a) must be covered.[54]

Children who are enrolled in an HCBS waiver program are also entitled to all EPSDT services.

States may also choose to offer services to children under section 1915(j) (self-directed personal assistance services), section 1915(k) (home and community-based attendant services and support) and section 1945 (coordinated care in

[53] Section 1915(c) of the Social Security Act.
[54] CMS, Dear State Medicaid Director, Olmstead Update No. 4, Att. 4-B (Jan. 10, 2001).

health homes for individuals with chronic conditions). Like services provided pursuant to a 1915(c) waiver, these services are not subject to EPSDT coverage provisions, but are instead available to supplement EPSDT services.

B. Alternative Benefit Plans

States must assure access to services available under the EPSDT benefit for all EPSDT-eligible children under age 21 enrolled in Alternative Benefit Plans (formerly known as benchmark plans and benchmark-equivalent plans).[55]

C. Role of Maternal and Child Health Services

Federal rules require state Medicaid agencies and Title V Maternal and Child Health (MCH) agencies and grantees to collaborate to assure better access to and receipt of the full range of screening, diagnostic, and treatment services covered under EPSDT.[56] Title V is administered by the Health Resources and Services Administration. Many state Medicaid agencies have entered into written agreements with their sister MCH programs and collaborate on improving access to EPSDT services in order to improve child health status. Among other things, cooperating MCH agencies can provide outreach, screening, diagnostic or treatment services, health education and counseling, case management and other assistance in achieving a comprehensive and effective child health benefit. MCH programs can also help Medicaid programs to enlist providers who can help deliver a broad array of services. In addition, they can inform potential and actual Medicaid recipients about EPSDT and refer them to necessary services.[57] CMS encourages such collaborations as MCH programs are crucial partners in the creation and delivery of a high quality, well-integrated child health benefit.

Many state Medicaid agencies have written agreements with their states' MCH programs and collaborate to improve access to EPSDT services.

[55] 42 C.F.R. § 440.345.
[56] 42 U.S.C. §§ 705(a)(5)(F), 709(a)(2); 42 C.F.R. § 441.61(c).
[57] CMS, State Medicaid Manual § 5230.

VII. ACCESS TO SERVICES

A. Access to Providers

Access to covered services is of course a critical component of delivering an appropriate health benefit to children. Accordingly, a number of Medicaid and EPSDT provisions are intended to assure that children have access to an adequate number and range of pediatric providers. For example, states are required to "make available a variety of individual and group providers qualified and willing to provide" services to children.[58] States must also "take advantage of all resources available" to provide a "broad base" of providers who treat children."[59] Some states may find it necessary to recruit new providers to meet children's needs.[60] In the event a child needs a treatment that is not coverable under the categories listed in section 1905(a), states are to provide referral assistance that includes giving the family or beneficiary the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.[61]

States are required to make available a variety of providers who are qualified and willing to treat EPSDT children.

A child is entitled to receive Medicaid services from any provider qualified to provide the service and willing to furnish it, unless CMS has decided that this "freedom of choice" requirement will not apply.[62] Most states have received permission from CMS to provide some services to some children through managed care arrangements that restrict the free choice of provider.

An appropriate level of reimbursement can be critical to ensuring adequate access to providers.[63] While the statute provides states with broad authority to set provider payment rates, it requires that payments to providers must be consistent with efficiency, economy, and quality care and be sufficient to enlist enough

[58] 42 C.F.R. § 441.61.
[59] CMS, State Medicaid Manual § 5220.
[60] *Id.*
[61] 42 C.F.R. § 441.61(a).
[62] Sections 1902(a)(23) and 1932(a) of the Social Security Act; 42 C.F.R. § 431.51(b).
[63] HCFA, Dear State Medicaid Director (Jan 18, 2001).

providers that care and services are available to Medicaid beneficiaries at least to the extent that they are available to the general population in the geographic area.[64]

Federal regulations provide that a Medicaid provider must agree to accept, as payment in full, the Medicaid payment for a covered service or item.[65] This means that a provider *may not* bill a Medicaid beneficiary for the difference between the provider's charge and the Medicaid payment (called "balance billing"). The payment in full requirement also prohibits Medicaid providers from billing beneficiaries for missed appointments. States may need to monitor compliance with this requirement.

Section 1905(a) lists coverable Medicaid services and some provider types. There are at least two means by which a state may cover a service by a provider type that is not specified in section 1905(a). Section 1905(a)(6) permits states to cover "medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law." Thus, a state may cover services performed by a class of providers (such as licensed dieticians) when the service they provide is not specified in section 1905(a) as long as the service is determined medically necessary for a child. Alternatively, a provider's services can be covered as a component of a section 1905(a) service. For example, in the case of a licensed social worker, the services could be provided through a federally qualified health center or a clinic, both of which are recognized providers under section 1905(a). The process for covering a provider for a service not specified in section 1905(a) varies depending on how the state intends to provide the service.

B. Managed Care

EPSDT benefits must be available to all children covered by Medicaid. As such, children enrolled in managed care plans, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case management systems (collectively referred to as managed care entities) are entitled to the same EPSDT benefits they would have in a fee for service Medicaid delivery system. Properly implemented, managed care can enhance and promote EPSDT's goals of ensuring that care is provided in a coordinated way and with an emphasis on prevention.

States are responsible for assuring that the full EPSDT benefit is available to all Medicaid children in the state, even if the state contracts with a managed care entity to deliver some or all of the services available under EPSDT. The state's

[64] Section 1902(a)(30)(A) of the Social Security Act; Medicaid Program: Methods for Assuring Access to Covered Medicaid Services, 76 Fed. Reg. 26,342 (May 11, 2011) (proposed regulations).
[65] 42 C.F.R. § 447.15.

contracts with managed care entities should be drafted with sufficient precision so that the entity's responsibilities with respect to children are clearly delineated. A contract can provide that the managed care entities will be responsible for providing services under the EPSDT benefit to the same degree that the services are covered by the state. Or, if certain responsibilities are carved out of the managed care contract, those carve-outs must be explicit, and the state will retain the responsibility for ensuring that those carved-out services are provided to enrolled children. For example, the state may 'carve out' dental services from the managed care contract; nonetheless, the state must assure that children receive those services (through either fee for service or a specialized dental plan).

Managed care entities may not use a definition of medical necessity for children that is more restrictive than the state's definition.

Managed care entities may not use a definition of medical necessity for children that is more restrictive than the state's definition. One way to ensure this is for the state to include its definition of medical necessity in the entity's contract. States should review managed care entities' medical necessity definitions and criteria to ascertain whether they meet this requirement. As a further step to provide for consistency across the delivery system and proper implementation of the children's benefit package, it is the state's responsibility to educate its contracted managed care entities about EPSDT requirements, as well as to verify that managed care providers are informed about EPSDT requirements through trainings and provider manuals. Further, states are responsible for ensuring that managed care entities fulfill their contractual responsibilities to inform all families of the services available under EPSDT and how to access them.[66] Information made available to enrollees, usually included in a member handbook, should clearly explain which EPSDT services the managed care entity will provide and how any EPSDT services not within the scope of the contract can be accessed by enrollees. Managed care entities must make available to all enrolled children the entire scope of services included in the EPSDT benefit that is within their contract with the state.[67]

[66] Sections 1902(a)(5) and (a)(43) of the Social Security Act.
[67] 42 C.F.R. § 438.210(a)(4).

Managed care entities must demonstrate to the state that they have adequate provider capacity in the plan to serve enrolled children, including an appropriate range of pediatric and specialty services; access to primary and preventive care; and a sufficient number, mix and geographic distribution of providers.[68]

Monitoring managed care entities' compliance with EPSDT requirements is essential; a strong oversight framework ensures that states are meeting their responsibilities to children as well as Federal monitoring requirements.[69] There are several methods of exercising effective oversight in managed care systems.

First, states contracting with managed care organizations (MCOs) or prepaid inpatient health plans (PIHPs) are statutorily required to draft, implement, and maintain a managed care quality strategy.[70] The quality strategy is intended to provide a blueprint for states in assessing and improving the quality of care provided to managed care enrollees.[71] By means of this strategy, states can monitor and evaluate managed care entities' compliance with quality initiatives, track their performance on specified performance measures, and require them to design, implement and report the results of performance improvement projects.

Second, states are also required to ensure that external quality review of MCOs and PHIPs are performed by unbiased, external entities.[72] In this way, states can determine whether managed care entities are reporting accurate performance outcomes data and whether they are in compliance with state contract provisions.

Third, states can engage in an ongoing review of grievances and appeals related to children's services, as well as monitoring complaints filed with the state's enrollee and provider hotlines (if the state operates such hotlines). States could also require reports and perform data analysis of managed care entities' encounter data to detect underutilization of services by children.

In addition, all states are required to complete and file the Form 416 each year.[73] This reports the number of children receiving health screening services, dental and oral health services, and referrals for corrective treatment, as well as the state's rates of meeting EPSDT participation goals.

[68] 42 C.F.R. § 438.206.
[69] 42 C.F.R. § 438.240.
[70] Section 1932(c)(1) of the Social Security Act; 42 C.F.R. §§ 438.202, 438.204.
[71] 42 C.F.R. § 438.202.
[72] Section 1932(c)(2) of the Social Security Act; 42 C.F.R. § 438.350.
[73] Section 1902(a)(43)(D) of the Social Security Act.

C. Timeliness

Services under the EPSDT benefit, like all Medicaid services, must be provided with "reasonable promptness."[74] The state must set standards to ensure that EPSDT services are provided consistent with reasonable standards of medical and dental practice. The state must also ensure that services are initiated within a reasonable period of time. What is reasonable depends on the nature of the service and the needs of the individual child. Because states have the obligation to "arrang[e] for . . . corrective treatment" either directly or through referral to appropriate providers, a lack of providers does not automatically relieve a state of its obligation to ensure that services are provided in a timely manner. For example, as noted above, it may be necessary to cover services provided out of state.

Services under the EPSDT benefit, like all Medicaid services, must be provided with reasonable promptness.

[74] Section 1902(a)(8) of the Social Security Act.

VIII. NOTICE AND HEARING REQUIREMENTS

Children under age 21, like all other people enrolled in Medicaid, have the right to notice and an opportunity for a hearing. If a state or managed care entity takes an "action" – to deny, terminate, suspend, or reduce a requested treatment or service, it must give the beneficiary written notice of the action and of their right to a hearing (a pre-termination hearing, in instances where services are reduced or terminated), including instructions on how to request a hearing.[75] When services are being terminated or reduced, the notice must be sent at least ten days before the effective date of the action.[76] Under exceptional circumstances, the notice must be mailed no later than the day of the action, such as when the beneficiary's physician prescribes a change in treatment or the beneficiary has been admitted to an institution and is no longer eligible.[77] The notice must contain a statement of the intended action, the specific reasons and legal support for the action, and an explanation of the individual's hearing rights, rights to representation and to continued benefits.[78]

If a state or managed care entity takes an action to deny, terminate, suspend, or reduce a requested treatment or service, it must give the beneficiary written notice of the action and of their right to a hearing.

The beneficiary is entitled to a hearing before the state Medicaid agency, or, if a state's hearing process provides for it, an evidentiary hearing at the local level (for example at a county department of social services) with a right of appeal to the state agency.[79] The hearing must be conducted at a reasonable time, date, and place by an impartial hearing official. A beneficiary must be allowed to present his or her case to an impartial decision maker and present evidence and

[75] Section 1902(a)(3) of the Social Security Act; *Goldberg v. Kelly*, 397 U.S. 254 (1970).
[76] 42 C.F.R. § 431.211.
[77] 42 C.F.R. § 431.213.
[78] 42 C.F.R. §§ 431.206, 431.210.
[79] 42 C.F.R. § 431.205(b).

witnesses.[80] The beneficiary is also entitled to have representation, including legal counsel, a relative, or a friend.[81] Before the hearing, beneficiaries must have the right to examine the case file and all documents that will be used at the hearing.[82]

When a service is terminated or reduced, if the beneficiary requests a hearing within ten days of receiving notice of the termination or reduction, the beneficiary has the right to continued coverage of services pending a hearing decision.[83] This is sometimes called "aid paid pending." Once the agency issues a final decision, the beneficiary generally has the right to appeal that decision to state court.

Managed care enrollees must have access to in-plan grievance and appeal processes, in addition to the state fair hearing system.[84] Managed care plans must provide enrollees written notices that explain the action, the reason for the action, and the procedures for using the in-plan grievance and state fair hearing processes, including rights to continued benefits. Managed care plans must resolve complaints in a timely manner, including within three working days when the enrollee or provider indicates that delay could seriously jeopardize the enrollee's life, health or ability to attain, maintain, or retain maximum function.[85] The state can require enrollees to exhaust the plan's internal grievance process before obtaining a state fair hearing.

The state agency must issue and publicize its hearing decisions.[86] In addition, the public must have access to all fair hearing decisions, subject to regulatory requirements providing for safeguarding of confidential personal and health information.[87]

[80] 42 C.F.R. §§ 431.240, 431.242.
[81] 42 C.F.R. § 431.206(b)(3).
[82] 42 C.F.R. § 431.242.
[83] 42 C.F.R. § 431.230.
[84] 42 C.F.R. § 438.402.
[85] 42 C.F.R. § 438.408.
[86] 42 C.F.R. § 431.206(a).
[87] 42 C.F.R. § 431.244(g).

IX. CONCLUSION

The goal of EPSDT is to assure that all Medicaid-enrolled children under age 21 receive the health care they need. EPSDT covers not only medically necessary treatment to correct or ameliorate identified conditions, but also preventive, and maintenance services. In addition, EPSDT covers age-appropriate medical, dental, vision and hearing screening services at specified times, and when health problems arise or are suspected.

The broad scope of EPSDT provides states with the tools necessary to offer a comprehensive, high-quality health benefit. To fully realize EPSDT's potential, however, attention is needed on issues affecting access to services, including supply of providers, the presence of managed care, linguistic and disability access, and transportation. CMS is available to help states address these issues to ensure that EPSDT coverage meets the needs of children under age 21 who depend on Medicaid for their health care.

X. WHAT YOU NEED TO KNOW ABOUT EPSDT

EARLY: Assessing and identifying problems early

Children covered by Medicaid are more likely to be born with low birth weights, have poor health, have developmental delays or learning disorders, or have medical conditions (e.g., asthma) requiring ongoing use of prescription drugs. Medicaid helps these children and adolescents receive quality health care.

EPSDT is a key part of Medicaid for children and adolescents. EPSDT emphasizes preventive and comprehensive care. Prevention can help ensure the early identification, diagnosis, and treatment of conditions before they become more complex and costly to treat. It is important that children and adolescents enrolled in Medicaid receive all recommended preventive services and any medical treatment needed to promote healthy growth and development.

PERIODIC: Checking children's health at age-appropriate intervals

As they grow, infants, children and adolescents should see their health care providers regularly. Each state develops its own "periodicity schedule" showing the check-ups recommended at each age. These are often based on the American Academy of Pediatrics' Bright Futures guidelines: Recommendations for Preventive Pediatric Health Care. Bright Futures helps doctors and families understand the types of care that infants, children and adolescents should get and when they should get it. The goal of Bright Futures is to help health care providers offer prevention-based, family-focused, and developmentally-oriented care for all children and adolescents. Children and adolescents are also entitled to receive additional check-ups when a condition or problem is suspected.

SCREENING: Providing physical, mental, developmental, dental, hearing, vision and other screening tests to detect potential problems

All infants, children and adolescents should receive regular well-child check-ups of their physical and mental health, growth, development, and nutritional status. A well-child check-up includes:

- A comprehensive health and developmental history, including both physical and mental health development assessments;
- Physical exam;
- Age-appropriate immunizations;
- Vision and hearing tests;
- Dental exam;
- Laboratory tests, including blood lead level assessments at certain ages; and
- Health education, including anticipatory guidance.

DIAGNOSTIC: Performing diagnostic tests to follow up when a health risk is identified

When a well-child check-up or other visit to a health care professional shows that a child or adolescent might have a health problem, follow up diagnostic testing and evaluations must be provided under EPSDT. Diagnosis of mental health, substance use, vision, hearing and dental problems is included. Also included are any necessary referrals so that the child or adolescent receives all needed treatment.

TREATMENT: Correct, reduce or control health problems found

EPSDT covers health care, treatment and other measures necessary to correct or ameliorate the child or adolescent's physical or mental conditions found by a screening or a diagnostic procedure. In general, States must ensure the provision of, and pay for, any treatment that is considered "medically necessary" for the child or adolescent. This includes treatment for any vision and hearing problems, including eyeglasses and hearing aids. For children's oral health, coverage includes regular preventive dental care and treatment to relieve pain and infections, restore teeth, and maintain dental health. Some orthodontia is also covered.

XI. RESOURCES

CMS Resources

- CMS, *State Medicaid Manual §§ 2700.4 and 5010-5360*
- CMS, *Early and Periodic Screening Diagnostic and Treatment Resources*

Adolescent Health

- CMS, *Paving the Road to Good Health: Strategies for Increasing Medicaid Adolescent Well-Care Visits (Feb. 2014)*

Oral Health

- CMS, *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children and Adolescents* (September 2013)
- CMS, *Improving Access to and Utilization of Oral Health Services for Children in Medicaid and CHIP Programs,* CMS Oral Health Strategy (April 11, 2011)
- CMS, *CMCS Informational Bulletin, CMS Oral Health Initiative and Other Dental Related Issues* (April 18, 2013)
- *Improving Oral Health Care Delivery in Medicaid and CHIP: A Toolkit for States* (February 2014)

Mental Health

- CMS, *CMCS Informational Bulletin, Prevention and Early Identification of Mental Health and Substance Use Conditions* (March 27, 2013)
- CMS, *Joint CMCS and SAMHSA Informational Bulletin, Coverage of Behavioral Health Services for Children, Youth, and Young Adults with Significant Mental Health Conditions* (May 7, 2013)

Screening Services

- CMS, *Guide for States Interested in Transitioning to Targeted Blood Lead Screening for Medicaid-eligible Children* (May 2012)

Accessibility

- CMS, *CMCS Informational Bulletin* (April 26, 2011) (federal funding for interpretation and translation services)
- CMS, *Dear State Medicaid Director* (Aug. 31, 2000) (Limited English Proficiency)
- CMS, *Dear State Medicaid Director, Olmstead Update No. 4*, Att. 4-B EPSDT (Jan. 10, 2001)
- CMS, *Medicaid School-Based Administrative Claiming Guide* (May 2003)

Other Federal Resources

- CDC, Vaccine Recommendations of the ACIP
- HRSA, *EPSDT & Title V Collaboration to Improve Child Health*
- Health Resources and Services Administration EPSDT website
- HHS Office of Minority Health's *Think Cultural Health: Advancing Health Equity at Every Point of Contact*
- HHS Office of Minority Health's *A Physician's Practical Guide to Culturally Competent Care*
- HHS Office of Minority Health's *Culturally Competent Nursing Care: A Cornerstone of Caring*
- HHS Office of Minority Health's *Cultural Competency Curriculum for Disaster Preparedness and Crisis Response*
- HHS Office of Minority Health's *Cultural Competency Program for Oral Health Professionals*
- HHS Office of Minority Health's *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards)*
- HHS Office of Minority Health's *A Blueprint for Advancing and Sustaining CLAS Policy and Practice (The Blueprint)*

Other Resources

- American Academy of Pediatrics, *Bright Futures* (2014)
- American Academy of Pediatrics, *Bright Futures Recommendations for Pediatric Preventive Care* (2014)
- American Academy of Pediatric Dentistry, *Guideline on Periodicity of Examination, Preventive Dental Services, Anticipatory Guidance/Counseling, and Oral Treatment for Infants, Children, and Adolescents* (2013)
- Association of Maternal and Child Health Programs, *Standards for Systems of Care for Children and Youth with Special Health Care Needs* (March 2014)
- George Washington University, Health Information & The Law, *Understanding the Interaction Between EPSDT and Federal Health Information Privacy and Confidentiality Laws* (2013)
- National Academy of State Health Policy, Managing the "T" in EPSDT Services (2010)
- National Academy of State Health Policy, Resources to Improve Medicaid for Children and Adolescents
- National Health Law Program, Toward a Healthy Future: Medicaid EPSDT Services for Poor Children and Youth
- National Health Law Program, Annotated Federal Documents

TAB 176-23

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Center for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
Center for Medicaid & CHIP Services

CMCS Informational Bulletin

DATE: July 21, 2022

FROM: Daniel Tsai, Deputy Administrator and Director
Center for Medicaid and CHIP Services

SUBJECT: Beneficiary Protections and Medicaid Drug Coverage - Under Value Based Purchasing (VBP) and Other Innovative Payment Arrangements

The purpose of this Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB) is to remind states and stakeholders of existing federal beneficiary protections that help ensure appropriate beneficiary access to prescription medications, especially as state programs and stakeholders continue to negotiate novel payment arrangements with drug manufacturers.

The Centers for Medicare & Medicaid Services (CMS) understand the challenges that states face managing pharmacy costs, especially as new, innovative gene and cell therapies are brought to market. We are taking several steps to help states meet these challenges. We have approved 13 state plan amendments (SPAs) that authorize states to negotiate with manufacturers for value-based supplemental rebates for a drug, and several more states' SPAs are under review. Moreover, we are issuing this CIB to coincide with the start of the new flexibilities that allow manufacturers to report to the agency multiple best prices for a drug that are connected to a VBP arrangement (as defined at 42 CFR 447.502) and made available to all states. These VBP arrangements will hold manufacturers more accountable for the clinical outcomes of their drugs, while giving more states the opportunity to earn additional rebates depending on how a drug works for patients. In addition, we look forward to working with states through a learning collaborative that will be launched in the fall of 2022 to help states better manage their pharmacy costs, especially for these high cost drugs. We hope this work will lead to productive negotiations between states and manufacturers regarding the cost of these drugs for Medicaid beneficiaries.

Introduction

Alternative VBP arrangements for drugs, such as outcomes-based models and supplemental rebate agreements, have become more commonplace. These arrangements allow state Medicaid agencies to receive additional discounts or rebates from manufacturers on a drug when a drug does not meet certain observed or expected therapeutic or clinical values in a select population, based on applicable evidence-based or outcomes-based measures. As a result of these new payment arrangements, we believe it is important that beneficiaries, states, and manufacturers understand the beneficiary protections currently in

place to ensure access to medications under both traditional pharmacy programs and alternative payment arrangements.

In the December 31, 2020 issue of the *Federal Register*, the CMS published the final rule entitled: *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements* (hereinafter referred to as the December 2020 final rule) (85 Fed. Reg. 87000; CMS 2482-F2). This new regulation permits manufacturers to report multiple best prices for a covered outpatient drug in certain cases. More specifically, it provides that if a manufacturer offers a VBP arrangement to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that VBP arrangement. These arrangements offered by manufacturers to states must meet the definition of a VBP arrangement as specified in 42 CFR § 447.502 and allow the state to collect additional rebates based on a patient's outcomes beyond those that the state will already receive under the Medicaid Drug Rebate Program (MDRP).

We note that states are not required to participate in these VBP arrangements in order for manufacturers to report multiple best prices. In addition to the states' voluntary participation in commercially-available VBP arrangements, states have also been actively negotiating other types of payment arrangements with manufacturers, such as through CMS-authorized supplemental rebate agreements, pay-over-time models, and "subscription" model arrangements under which the manufacturer charges a payer a fixed amount for an unlimited supply of a drug (resulting in a lower per unit price as utilization of the drug increases). Regardless of the type of arrangement, CMS is providing this guidance to ensure that stakeholders are aware of laws and regulations regarding beneficiaries' access to medically necessary medications.

Medicaid Requirements that Protect Beneficiary Access to Drugs

CMS believes it is important to reiterate to states and manufacturers the current federal protections that are in place under the Medicaid program to help ensure appropriate beneficiary access to drugs. States must generally apply these existing broad statutory requirements to Medicaid coverage of prescription drugs, regardless of any type of payment arrangement the state may have with manufacturers, unless an exception applies, such as a waiver.

1. States must cover all covered outpatient drugs subject to a rebate agreement with the Secretary: States must cover all covered outpatient drugs of a manufacturer that has entered into and has in effect a Medicaid drug rebate agreement, and may only restrict or exclude coverage of drugs as expressly described in section 1927(d) of the Social Security Act (the Act). Subject to these permissible restrictions, covered outpatient drugs that are prescribed for a medically accepted indication must be covered. States are permitted to subject any drug to prior authorization as long as it meets the requirements of section 1927(d)(5).

   Section 1927(d)(1)(B) of the Act permits states to restrict or exclude coverage of a covered outpatient drug only if the prescribed use is not for a medically accepted indication, the drug is included in the list of drugs or drug classes (or their medical uses) that may be excluded or otherwise restricted by the state (e.g., agents when used for cosmetic purposes or to promote fertility), the drug is subject to restrictions

pursuant to an authorized agreement between the manufacturer and state under a permissible prior authorization program or formulary, or pursuant to a state established formulary that is consistent with federal law.

Section 1927(d)(6) permits states to impose limitations with respect to all such drugs in a therapeutic class, on minimum or maximum quantities per prescription or on the number of refills, if such limitations discourage waste, and may address instances of fraud and abuse. The statute also further provides an enumerated list of non-excludable drugs, classes of drug, or their medical uses at section 1927(d)(7), which a state may not exclude from coverage. In summary, a state must ensure the covered outpatient drugs of a manufacturer with an effective Medicaid drug rebate agreement are covered and available when the covered outpatient drug is prescribed for a medically accepted indication, unless certain exclusions or restrictions apply.

2. State Alternative Benefit Plans (ABP) must follow Essential Health Benefit (EHB) standards when providing prescription drug coverage: When providing coverage under alternative benefit plans to a Medicaid population, states are required to provide prescription drug coverage that meets certain specific drug formulary standards, and to have a process in place such that the Medicaid beneficiary can access clinically appropriate drugs not covered on the state's drug formulary. Specifically, under 42 CFR § 440.347(a)(6), states must provide prescription drug coverage that meets the Essential Health Benefits (EHB) standards described in 45 CFR § 156.122, including a formulary that meets the standards at 45 CFR § 156.122(a), and that includes a process in place that allows the Medicaid beneficiary (or their designee) to request and gain access to clinically appropriate drugs not otherwise covered by the formulary consistent with the EHB standard at 45 CFR § 156.122(c). As specified at 42 CFR § 440.347(e), EHBs cannot be based on a benefit design or implementation of a benefit design that discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions.

3. States generally cannot limit beneficiary access to certain providers because of a specific payment arrangement: In general, section 1902(a)(23)(A) of the Act and 42 CFR § 431.51(b) require that any Medicaid beneficiary may obtain Medicaid services (including covered outpatient drugs) from any institution, agency, pharmacy, person, or organization that is qualified to furnish the service or services, and willing to furnish them to that particular beneficiary. CMS can waive this requirement under section 1915(b) or section 1115 of the Act, and this requirement also would not generally apply under state plan Medicaid managed care programs. Therefore, unless this requirement has been waived, is not applicable, or an exception applies, a state may not limit coverage of drugs to those obtained from a limited list of Medicaid providers or pharmacies. Additionally, under certain circumstances specified in 42 CFR § 431.52, states are required to cover Medicaid services provided out of state to their residents who are Medicaid beneficiaries and who are absent from the state.

4. States generally must comply with the Medicaid comparability requirement: Unless an exception applies or this requirement is waived under section 1115 of the Act, section 1902(a)(10)(B) of the Act and 42 CFR § 440.240 require states to ensure that the services available to any categorically needy beneficiary under the Medicaid state plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary. Also, unless an exception applies or the requirement is waived, these provisions require states to ensure that the services available to any

individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group: (1) the categorically needy; and (2) a covered medically needy group. Therefore, any payment arrangement a state enters into must result in compliance with these comparability requirements, unless an exception applies or the requirements have been waived.

5. States must adhere to Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements: Under section 1905(a)(4)(B) and (r) of the Act, states are required to cover all medically necessary services described in section 1905(a) of the Act for children under the age of 21 who are eligible for EPSDT, including prescribed drugs, regardless of any payment arrangement. What this means is that any prescribed drug covered under Medicaid EPSDT requirements is eligible for federal financial participation (FFP), regardless of the applicability of section 1927. In other words, even if the drug is not a covered outpatient drug in accordance with section 1927(k)(2) of the Act or the drug is a covered outpatient drug and a manufacturer does not have in effect a drug rebate agreement, the drug is covered under Medicaid and is eligible for FFP if prescribed under EPSDT requirements.

6. States must continue to have Drug Utilization Review (DUR) Programs in place: As required under section 1927(g) of the Act, a state must continue to have a DUR program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the state's Medicaid program. The DUR program operates to help ensure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results for Medicaid beneficiaries. Each state DUR program must consist of prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities. States must continue to apply DUR requirements to covered outpatient drugs regardless of how the state pays for the drug.

Other Federal Laws and Regulations Protecting Medicaid Beneficiaries

There are other federal laws and regulations that states and manufacturers must review and follow in addition to the specific Medicaid statutory and regulatory requirements discussed above. Below, we identify some federal laws that provide additional protection to beneficiaries that states and manufacturers should remain mindful of as they pursue any payment arrangement, however, this does not constitute an exhaustive list of all applicable federal laws and regulations.

1. All parties must comply with the federal fraud and abuse laws: For example, federal anti-kickback provisions at section 1128B(b) of the Act makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a federal health care program. The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a federal health care program. For purposes of the federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The federal anti-kickback statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a federal health care program. The Office of Inspector General (OIG), Department of Health and Human Services (HHS) has promulgated certain

safe harbors potentially applicable to certain value based arrangements, *see, e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements* (https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf). In addition, parties may request an advisory opinion[1] from HHS-OIG regarding the application of HHS-OIG's fraud and abuse authorities, including those related to the federal anti-kickback statute, to the party's existing or proposed arrangement.

2. States must comply with federal civil rights laws: Civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex (including pregnancy, sexual orientation and gender identity), age, and disability continue to apply when states participate in any payment arrangement. These laws include Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (race, color, national origin, sex (including pregnancy, sexual orientation and gender identity), age, and disability in health programs and activities), Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d *et seq*. (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. §§ 1681 *et seq*. (sex (including pregnancy, sexual orientation, and gender identity) in education programs and activities), the Age Discrimination Act of 1975, 42 U.S.C. §§ 6101 *et seq*. (age), Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (disability), and the Americans with Disabilities Act, 42 U.S.C. §§ 12101 *et seq*. (disability). In accordance with these legal obligations, we noted in the December 2020 rule (85 FR 87014) that manufacturers and payers, including state Medicaid agencies, may not make use of measures that would unlawfully discriminate on the basis of disability or age, among other bases, when designing or participating in VBP arrangements. We further noted at 85 FR 87016, that VBP measures should not endanger certain patients, providers, or impede access to other available medications and treatments, or interfere with the practice of medicine generally.

3. States must comply with applicable privacy and security laws: Privacy and security laws and regulations, such as those under the Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104-191), must be considered when states participate in arrangements that require reporting and recording of patient-specific outcomes data for evaluation to determine payment when payment is tied to outcomes. This is especially important with respect to lower-utilized drugs when disclosure of individually identifiable health information may lead to privacy concerns. Such information should only be used or disclosed in accordance with applicable privacy and security laws, which may limit use or disclosure to the minimum necessary data.

Available Enforcement Mechanisms for CMS

If CMS becomes aware of potential state compliance concerns related to the specific Medicaid requirements discussed above, CMS will first work with the state to help its Medicaid program come into compliance with the applicable laws and regulations. As a next step, when necessary, CMS may review state and local administration of Medicaid programs through an analysis of the state's policies and procedures, on-site review of selected aspects of agency operations, and examination of samples of

[1] Advisory Opinion Process | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov)

individual case records, in accordance with 42 CFR § 430.32. If these reviews reveal serious problems with respect to state compliance with any federal requirement, or with the state's approved state plan, CMS will request the state to correct its practice. After CMS provides a *notice of non-compliance,* with a request to the state to develop a corrective action plan, if the state fails to comply after being notified and given an opportunity for a hearing, CMS may withhold FFP for non-compliance. The withholding may continue until CMS is satisfied that the state's practices are in compliance with federal requirements (see 42 CFR § 430.35).

CMS does not enforce the non-Medicaid related federal requirements summarized above and will work with the HHS-OIG or the HHS Office for Civil Rights if we believe there are potential compliance issues. CMS may also refer any findings specific to manufacturer drug pricing and drug product related reporting activity to the HHS-OIG.

Conclusion

CMS' policy goal with respect to the MDRP, and state adoption of manufacturers' VBP arrangements, as well as participation in other novel payment arrangements, is to further increase access to high cost therapies for underserved populations, and reduce health disparities. This bulletin reminds states that choose to enter into these arrangements of the range of federally-based protections available to Medicaid beneficiaries. CMS will continue to monitor state Medicaid drug coverage under such arrangements to ensure it remains consistent with the Medicaid statutory and regulatory requirements and that Medicaid beneficiaries can access all medically necessary prescription medications.

For further information regarding this CIB, you may contact John M. Coster, Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov.

TAB 176-29

April 18, 2016

The U.S. Commission on Civil Rights Statement Condemning Recent State Laws and Pending Proposals Targeting the Lesbian, Gay, Bisexual, and Transgender Community

The United States Commission on Civil Rights, by a majority vote, strongly condemns recent state laws passed, and proposals being considered, under the guise of so-called "religious liberty" which target members of the lesbian, gay, bisexual, and transgender ("LGBT") community for discrimination.

North Carolina Governor Pat McCrory recently signed into law H.B. 2, legislation blocking local governments from passing anti-discrimination rules that grant protections to gay and transgender persons. The law also repeals existing municipal anti-discrimination laws which protected LGBT people from bias in housing and employment. Critically, the new legislation also forces transgender people to utilize public bathrooms and changing facilities based on the sex issued on their birth certificates, and not according to their gender identities. This jeopardizes not only the dignity, but also the actual physical safety, of transgender people whose appearances may not match societal expectations of the sex specified on their identification documents.

In Mississippi, Governor Phil Bryant recently signed HB 1523 into law. The new statute is far- reaching and allows people with "religious objections" to deny wedding services to same-sex couples. It also clears the way for employers to cite religion in determining workplace policies on dress code, grooming and bathroom access. The physical safety concerns for transgender people are the same as in North Carolina.

The laws enacted in North Carolina and Mississippi are not isolated, but are part of a larger, alarming trend to limit the civil rights of a class of people using religious beliefs as the excuse. Similar laws were passed by the legislatures in Georgia and Virginia, but those were vetoed

after significant public pressure. The Tennessee legislature just passed a bill which, if signed by Governor Bill Haslam, will permit mental health professionals to deny counseling services to LGBT people based upon "sincerely held religious beliefs." Kansas is considering a non-legislative, administrative policy change which would make it more difficult for transgender people to change the sex listed on their birth certificates. These laws and policies can be found to violate the Equal Protection and Due Process clauses of the Fourteenth Amendment. These laws can also be found to violate Title IX of the Education Amendments of 1972, which forbids discrimination against transgender students in any school that receives federal funding.

The Commission recently approved a report, which will be released shortly, on the issue of religious liberty. In our findings and recommendations the Commission makes clear:

- Civil rights protections ensuring nondiscrimination, as embodied in the Constitution, laws, and policies, are of preeminent importance in American jurisprudence.
- Religious exemptions to the protections of civil rights based upon classifications such as race, color, national origin, sex, disability status, sexual orientation, and gender identity, when they are permissible, significantly infringe upon these civil rights.
- Overly broad religious exemptions unduly burden nondiscrimination laws and policies. Federal and state courts, lawmakers, and policy-makers at every level must tailor religious exceptions to civil liberties and civil rights protections as narrowly as applicable law requires.

Commission Chairman Martin R. Castro stated on behalf of the Commission, "Religious freedom is an important foundation of our nation. However, in the past, 'religious liberty' has been used to block racial integration and anti-discrimination laws. Those past efforts failed and this new attempt to revive an old evasive tactic should be rejected as well. The North Carolina and Mississippi laws, and similar legislation proposed in other states, perverts the meaning of religious liberty and perpetuates homophobia, transphobia, marginalizes the transgender and gay community and has no place in our society.

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The U.S. Commission on Civil Rights is an independent, bipartisan agency charged with advising the President and Congress on civil rights matters and issuing a federal civil rights enforcement report. For information about Commission's reports and meetings, visit http://www.usccr.gov.

TAB 176-31

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

NCD 140.3, Transsexual Surgery
Docket No. A-13-87
Decision No. 2576
May 30, 2014

DECISION

The Board has determined that the National Coverage Determination (NCD) denying Medicare coverage of all transsexual surgery as a treatment for transsexualism is not valid under the "reasonableness standard" the Board applies. The NCD was based on information compiled in 1981. The record developed before the Board in response to a complaint filed by the aggrieved party (AP), a Medicare beneficiary denied coverage, shows that even assuming the NCD's exclusion of coverage at the time the NCD was adopted was reasonable, that coverage exclusion is no longer reasonable. This record includes expert medical testimony and studies published in the years after publication of the NCD. The Centers for Medicare & Medicaid Services (CMS), which is responsible for issuing and revising NCDs, did not defend the NCD or the NCD record in this proceeding and did not challenge any of the new evidence submitted to the Board.

Effect of this decision

Since the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery, and local coverage determinations (LCDs) used to adjudicate such claims may not rely on the provisions of the NCD. The decision does not bar CMS or its contractors from denying individual claims for payment for transsexual surgery for other reasons permitted by law. Nor does the decision address treatments for transsexualism other than transsexual surgery. The decision does not require CMS to revise the NCD or issue a new NCD, although CMS, of course, may choose to do so. CMS may not reinstate the invalidated NCD unless it has a different basis than that evaluated by the Board. 42 C.F.R. § 426.563.

CMS must implement this Board decision within 30 days and apply any resulting policy changes to claims or service requests made by Medicare beneficiaries other than the AP for any dates of service after that implementation. With respect to the AP's claim in

particular, CMS and its contractors must "adjudicate the claim without using the provision(s) of the NCD that the Board found invalid." 42 C.F.R. § 426.560(b)(1).[1]

Legal background

With exceptions not relevant here, section 1862(a)(l)(A) of the Social Security Act (Act) (42 U.S.C. § 1395y(a)(l)(A)) bars Medicare payment for items or services "not reasonable and necessary for the diagnosis or treatment of illness or injury[.]"[2] CMS refers to this requirement as the "medical necessity provision." 67 Fed. Reg. 54,534, 54,536 (Aug. 22, 2002). An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Act §§ 1862(l)(6)(A),1869(f)(1)(B); *see also* 42 C.F.R. § 400.202 (NCD "means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. at 54,535. When CMS issues NCDs, they apply nationally and are binding at all levels of administrative review of Medicare claims. 42 C.F.R. § 405.1060. CMS and its contractors use applicable NCDs in determining whether a beneficiary may receive Medicare reimbursement for a particular item or service. 42 C.F.R. §§ 405.920, 405.921.

A Medicare beneficiary "in need of coverage for a service that is denied based on … an NCD" is an "aggrieved party" who may challenge the NCD by filing a "complaint" with the Board.[3] Act § 1869(f)(1); 42 C.F.R. §§ 426.110, 426.320. The complaint must comply with the requirements for a valid complaint in 42 C.F.R. § 426.500 in order to be accepted by the Board. 42 C.F.R. §§ 426.510(b)(2), 426.505(c)(2). After the Board notifies CMS of the receipt of a complaint that is acceptable under the regulations, CMS produces the "NCD record," which "consists of any document or material that CMS

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[1] *See generally* 42 C.F.R. § 426.560(b) (setting out the effects of a Board NCD decision); 42 C.F.R. § 426.555 (specifying what the Board's decision "may not do"). This decision has no effects beyond those set out in 42 C.F.R.§ 426.560(b) and does not impose on CMS or its contractors any orders or requirements prohibited by 42 C.F.R. § 426.555.

[2] The table of contents to the current version of the Social Security Act, with references to the corresponding United States Code chapter and sections, can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm.

[3] The regulations also provide that a person other than the aggrieved party with an interest in the issues may petition to participate in the review process as an amicus curiae. 42 C.F.R. §§ 426.510(f), 426.513. The Board posts on its website notice of the NCD complaint specifying a time period for requests to participate in the review. 42 C.F.R. § 426.510(f).

considered during the development of the NCD" including "medical evidence considered on or before the date the NCD was issued . . . ." 42 C.F.R. §§ 426.510(d)(3), 426.515, 426.518(a). The aggrieved party submits a statement "explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard," and CMS may submit a response "in order to defend the NCD." 42 C.F.R. § 426.525(a), (b). If the Board determines that the NCD record "is complete and adequate to support the validity of the NCD," the review process ends with the Board's "[i]ssuance of a decision finding the record complete and adequate to support the validity of the NCD . . . ." 42 C.F.R. § 426.525(c)(1), (2). If the Board determines that the record is *not* complete and adequate to support the validity of the NCD, the Board "permits discovery and the taking of evidence . . . and evaluates the NCD" in accordance with the requirements of Part 426, including conducting a hearing, unless the matter can be decided on the written record. 42 C.F.R. §§ 426.525(c)(3), 426.531(a)(2).

Prior to issuing a decision, the Board must review any "new evidence" admitted to the record before the Board and determine whether it "has the potential to significantly affect" the Board's evaluation. 42 C.F .R. §§ 426.340(a), (b), 426.505(d)(3). "New evidence" is defined as "clinical or scientific evidence that was not previously considered by … CMS before the … NCD was issued." 42 C.F.R. § 426.110. If the Board so concludes, the Board stays proceedings for CMS "to examine the new evidence, and to decide whether [to] initiate[] … a reconsideration" of the NCD. 42 C.F.R. § 426.340(d). If CMS does not reconsider the NCD, or reconsiders it but does not change the challenged provision, the Board lifts the stay and the NCD challenge process continues. 42 C.F.R. § 426.340(f). At the end of that process, the Board closes the record and issues a decision that the challenged "provision of the NCD is valid" or "is not valid under the reasonableness standard."[4] 42 C.F.R. § 426.550. The Board's decision "constitutes a final agency action and is subject to judicial review" on appeal by an aggrieved party. 42 C.F.R. § 426.566.

[4] Section 426.547(b) states that the Board must make the decision available at the HHS Medicare Internet site and that "the posted decision does not include any information that identifies any individual, provider of service, or supplier." CMS has indicated in the preamble to the Part 426 regulations that this provision was meant to protect the privacy of Medicare beneficiaries such as the AP. *See, e.g.*, 68 Fed. Reg. 63,692, 63,708 (Nov. 7, 2003) ("Board decisions regarding NCDs will be made available on the Medicare Internet site, without beneficiary identifying information").

Case background

The NCD and the NCD record

The challenged NCD, titled "140.3, Transsexual Surgery," states:[5]

> **Item/Service Description**
>
> Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses.
>
> **Indications and Limitations of Coverage**
>
> Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

NCD Record at 93. CMS's predecessor, the Health Care Financing Administration (HCFA), published the NCD in the Federal Register on August 21, 1989.[6] 54 Fed. Reg. 34,555, 34,572 (Aug. 21, 1989); NCD Record at 76, 78, 93, 128. The NCD quotes or paraphrases portions of an 11-page report that the former National Center for Health Care Technology (NCHCT) of the HHS Public Health Service (PHS) issued in 1981, titled

[5] NCDs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd.

[6] The Federal Register notice stated, "This notice lists those current Medicare national coverage decisions which have been issued in the Medicare Coverage Issues Manual (HCFA Pub. 6)." 54 Fed. Reg. at 34,555.

"Evaluation of Transsexual Surgery" (1981 report).[7] NCD Record at 13-23. The NCHCT forwarded the 1981 report to HCFA with a May 6, 1981 memorandum stating that the 1981 report "concludes that transsexual surgery should be considered experimental because of the lack of proven safety and efficacy of the procedures for the treatment of transsexualism" and recommending "that transsexual surgery not be covered by Medicare at this time." *Id.* at 12.

The NCD record includes three April 1982 letters from the American Civil Liberties Union (ACLU) of Southern California disagreeing with HCFA's noncoverage determination. *Id.* at 24-25, 26, 41-42. The ACLU submitted letters and affidavits from physicians and therapists supporting the medical necessity of transsexual surgery and taking issue with the non-coverage determination. *Id.* at 27-75. On May 11, 1982, the HCFA physicians panel, by a vote of five to two, recommended against referring the ACLU's submissions to PHS, "on the basis that it does not contain information about new clinical studies or other medical and scientific evidence sufficiently substantive to justify reopening the previous PHS assessment." *Id.* at 7, 9. Thus, although the NCD was issued in 1989, it was based on the analysis of medical and scientific publications in the 1981 report.

The NCD complaint

The AP in this case, a Medicare beneficiary whose insurer denied a physician's order for sex reassignment surgery (transsexual surgery), filed an acceptable NCD complaint and supporting materials. CMS submitted the NCD record on May 15, 2013, and the AP submitted a statement of why the NCD record is not complete or adequate to support the validity of the NCD under the reasonableness standard (AP Statement) on June 14, 2013. The Board granted unopposed requests by six advocacy organizations to participate as amici curiae in the NCD review by filing written briefs arguing that the NCD was invalid. (Four of the amici submitted a joint brief.)[8]

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[7] The concluding summary of the 1981 NCHTC report stated in relevant part:

> Transsexual surgery for sex reassignment of transsexuals is controversial. There is a lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism. There is evidence of a high rate of serious complications of these surgical procedures. The safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned. Therefore, transsexual surgery must be considered still experimental.

NCD Record at 19.

[8] The six amici are the Human Rights Campaign (HRC) and the World Professional Association for Transgender Health (WPATH), which each submitted briefs, and the FORGE Transgender Aging Network, the National Center for Transgender Equality, the Sylvia Rivera Law Project, and the Transgender Law Center, which submitted a joint brief.

On June 26, 2013, CMS notified the Board that it "declines to submit a response" to the AP's statement. On December 2, 2013, the Board ruled that the NCD record "is not complete and adequate to support the validity of the NCD[.]" *NCD 140.3, Transsexual Surgery*, NCD Ruling No. 2 (Dec. 2, 2013) (NCD Ruling).[9] The parties then jointly reported that they did not intend to submit additional evidence (except for curricula vitae (CVs) of the AP's witnesses) or cross-examine any witness and asked the Board to close the NCD review record to the taking of evidence and decide the case based on the written record.

The Board determined that the new evidence in the record had the potential to significantly affect its review of the NCD and, as required, stayed proceedings for 10 days for CMS to examine the new evidence and decide whether to reconsider the NCD.[10] *Order Closing Record & Staying Proceedings for CMS to Determine Whether to Reconsider NCD* (Feb. 25, 2014) (Order); 42 C.F.R. §§ 426.340(d), 426.505(d)(3). Two days later, CMS informed the Board by email that it "does not wish to reconsider the NCD." On February 28, 2014, the Board lifted the stay and informed the parties that it would proceed to decision.

The record developed before the Board

The record before the Board consists of the NCD record, the briefs submitted by the AP and the amici and evidence submitted by the AP and one of the amici, the Human Rights Campaign. Since neither party submitted argument or evidence (except for the CVs) after the Board's Ruling, the Board treats the AP statement as the AP's brief in this appeal.[11] The AP submitted written declarations made under penalty of perjury from a clinical psychologist and a physician, and two notarized physician letters submitted to an Administrative Law Judge in the Department of Health and Human Services Office of Medicare Hearings and Appeals in another matter. The AP described the witnesses, who are active in the field of treating transgender persons, as experts and submitted their resumes or CVs. AP Statement at 9; AP complaint; AP/CMS e-mail (Jan. 7, 2014).

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[9] The NCD Ruling is at http://www.hhs.gov/dab/decisions/dabdecisions/ncd1403.pdf.

[10] The Board also published on its website notice providing an additional time period for interested parties to submit participation requests; none were received.

[11] Most of the AP's evidence other than witness statements is an appendix of sources the clinical psychologist cited in her declaration. We refer to these materials as the AP's exhibits (AP Exs.) and cite to the page numbers used in the publications in which they appeared. In addition, the physician's declaration includes an appendix of 20 unnumbered pages of insurance regulations from four states and the District of Columbia barring exclusion of sex reassignment surgery as medically necessary treatment for severe gender dysphoria. One of the amici, the Human Rights Campaign, submitted 62 exhibits with its brief ("HRC Exs.").

CMS did not challenge the witnesses' qualifications as experts or seek to cross-examine them. We summarize their qualifications when we address their testimony below. In this decision we use the term "new evidence" to refer to the evidence submitted to us by the AP and amici to distinguish it from the evidence used to support the NCD which, as noted, consists principally of the 1981 report. Under the regulatory definition in 42 C.F.R. § 426.110, "new evidence" would also include any evidence submitted by CMS in response to an NCD complaint that was not considered by CMS before the NCD was issued. In this case, however, as we discuss below, CMS submitted no "new evidence."

Standard of review

The Board "evaluate[s] the reasonableness" of an NCD by determining whether it "is valid [or] is not valid under the reasonableness standard," which requires us to uphold the NCD "if the findings of fact, interpretations of law, and applications of fact to law by … CMS are reasonable" based on the NCD record and the relevant record developed before us. Act § 1869(f)(1)(A)(iii); 42 C.F.R. §§ 426.110, 426.531(a), 426.550(a). The Board "defer[s] only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(1)(A)(iii); 42 C.F.R. § 426.505(b).

During the review, the aggrieved party bears the burden of proof and the burden of persuasion for the issues raised in an NCD complaint; the burden of persuasion is judged by a preponderance of the evidence. 42 C.F.R. § 426.330. CMS has explained that "[s]o long as the outcome [in the NCD] is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld," and that if CMS "has a logical reason as to why some evidence is given more weight than other evidence," the Board "may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage." 68 Fed. Reg. at 63,703.

Analysis

The NCD is invalid because a preponderance of the evidence in the record as a whole supports a conclusion that the NCD's stated bases for its blanket denial of coverage for transsexual surgery are not reasonable.

As previously stated, the NCD was based principally on the 1981 report findings that the safety and effectiveness of transsexual surgery had not been proven. The AP argues that these findings are not "supportable by the current state of medical science" and "not reasonable in light of the current state of scientific and clinical evidence and current medical standards of care" and are contradicted by studies conducted in the 32 years since the 1981 report. AP Statement at 6-7, 14. The amici made similar arguments. *See, e.g.*, WPATH Br. at 13 ("since [the NCD] was issued, it has been repeatedly

demonstrated that SRS [sex reassignment surgery] is safe, effective, and indisputably necessary treatment for certain individuals with severe GID [gender identity disorder]"). As we discuss below, the new evidence, which is unchallenged, indicates that the bases stated in the NCD and the NCD record for denying coverage, even assuming they were reasonable when the NCD was issued, are no longer reasonable.

A. The fact that the new evidence is unchallenged and the NCD record undefended is significant.

As we stated earlier, the AP has the burden of proof by a preponderance of the evidence that an NCD is invalid under a reasonableness standard. In deciding whether the AP has met this burden, we must weigh the evidence in the record before us. Thus, we consider it important to note at the outset that the only evidence before us, other than the record for the NCD, which consists principally of the 1981 report, is the new evidence submitted by the AP and the amicus HRC. CMS submitted the NCD record, as it was required to do, but has not argued that that record or any other evidence supports the NCD. CMS also did not elect to cross-examine the AP's witnesses, has not challenged their testimony or professional qualifications and joined the AP in asking the Board to decide the appeal based on the written record. *See* AP/CMS e-mail (Jan. 7, 2014). The preamble to the regulations that implement the NCD statute states that the "reasonableness standard . . . recognizes the expertise of … CMS in the Medicare program—specifically, in the area of coverage requiring the exercise of clinical or scientific judgment." 68 Fed. Reg. at 63,703 (emphasis added). Accordingly, in determining whether the NCD is valid under the reasonableness standard, we must accord some deference to CMS's position, and its decision not to defend the NCD or challenge the new evidence in this case has some significance for our decision-making.

Apart from the absence of any challenge to the new evidence or defense of the NCD record, we find the new evidence credible and persuasive on its face.[12] We have no difficulty concluding that the new evidence, which includes medical studies published in the more than 32 years since issuance of the 1981 report underlying the NCD, outweighs the NCD record and demonstrates that transsexual surgery is safe and effective and not experimental. Thus, as we discuss below, the grounds for the NCD's exclusion of coverage are not reasonable, and the NCD is invalid.

[12] For this reason, we found it unnecessary to exercise our independent authority to "consult with appropriate scientific or clinical experts concerning clinical and scientific evidence." *See* 42 C.F.R. § 426.531(b).

B. The new evidence indicates acceptance of criteria for diagnosing transsexualism.

Transsexual surgery is a treatment option for the medical condition of transsexualism. The NCD recognized that transsexualism is a diagnosed medical condition. The 1981 report stated that transsexualism "is defined as an overwhelming desire to change anatomic sex stemming from the fixed conviction that one is a member of the opposite sex." NCD Record at 13, citing Dorland's Illustrated Medical Dictionary, 25th ed. The 1981 report recognized that the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders issued in 1980 (DSM III) had "included for the first time the diagnostic category of 'Transsexualism.'" NCD Record at 13. Nonetheless, the 1981 report expressed concern that diagnosing transsexualism was "problematic" because, the report contended, the criteria for establishing the diagnosis "vary from center to center and have changed over time." NCD Record at 14.

One of the AP's expert witnesses, Randi Ettner, Ph.D., a clinical psychologist, testified that the expressed basis for this concern is "completely untrue now." Ettner Supp. Decl. at ¶ 5. Dr. Ettner stated that "Gender Identity Disorder is a serious medical condition codified in the International Classification of Diseases (10th revision; World Health Organization) and the [DSM]."[13] Ettner Decl. at ¶ 10; *see also* Ettner Supp. Decl. at ¶ 6 (similar testimony). She described the condition as follows:

> The disorder is characterized by intense and persistent discomfort with one's primary and secondary sex characteristics—one's birth sex. The suffering that arises is often described as "being trapped in the wrong body." The psychiatric term for this severe and unremitting emotional pain is "gender dysphoria."

Ettner Decl. at ¶ 10. Dr. Ettner's declaration and CV state that she has a doctorate in psychology, has evaluated or treated between 2,500 and 3,000 individuals with GID and mental health issues related to gender variance, has published three books, including *Principles of Transgender Medicine and Surgery*, has authored articles in peer-reviewed journals, and is a member of the board of directors of the World Professional Association for Transgender Health (WPATH) and an author of the WPATH Standards of Care for

[13] The record indicates that the term "transsexualism" that was used in the NCD and the DSM-III was succeeded in the DSM-IV and DSM-V by the terms "Gender Identity Disorder" (GID) and "gender dysphoria." AP Statement at 1 n.1; Ettner Supp. Decl. at ¶ 6; Hsiao Decl. at ¶ 11; AP Ex. 7, at 208; WPATH Br. at 2 n.3. In this decision, we use the term "transsexualism" because it is used in the NCD, but our decision should be read as encompassing the successor terminology as well.

the Health of Transsexual, Transgender, and Gender-Nonconforming People. *Id.* at ¶¶ 3-6; *see also Sundstrom v. Frank*, 630 F. Supp. 2d 974, 986-87 (E.D.Wis. 2007) ("Dr. Ettner's experience speaks for itself … the doctor has conducted research and has been an instructor specializing in the etiology, diagnosis and treatment of GID [and] is the editor of a medical textbook in which she wrote the chapter of that book on the etiology of GID. The court finds that Dr. Ettner is sufficiently qualified to provide expert testimony.").

We find nothing in the new evidence that would undercut Dr. Ettner's statement. The DSM-IV-TR (text revision), published in 2000, continues to recognize "transsexualism" as a diagnosed medical condition, although it refers to the same disorder as GID and identifies criteria for diagnosing GID in adolescents and adults that are consistent with Dr. Ettner's description, albeit more detailed. The criteria include "strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex)" that is "manifested by symptoms such as a stated desire to be the other sex, frequent passing as the other sex, desire to live or be treated as the other sex, or the conviction that he or she has the typical feelings and reactions of the other sex;" "[p]ersistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex" that is "manifested by symptoms such as preoccupation with getting rid of primary and secondary sex characteristics (e.g., request for hormones, surgery, or other procedures to physically alter sexual characteristics to simulate the other sex) or belief that he or she was born the wrong sex;" and "[t]he disturbance is not concurrent with a physical intersex condition." AP Ex. 4, at 581. The DSM-IV-TR states that if GID is present in adults, "[t]he disturbance can be so pervasive that the mental lives of some individuals revolve only around those activities that lessen gender distress." *Id.* at 576, 78. The WPATH brief indicates that transsexualism or GID remains a diagnostic category in the fifth edition of the DSM issued in 2013 (DSM-V), which uses the term "Gender Dysphoria." WPATH Br. at 2, n.3.

The DSM has been recognized as a primary diagnostic tool of American psychiatry. *See O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, at 60 (2010) (stating "all three experts agree [that the DSM-IV-TR] is the primary diagnostic tool of American psychiatry"); *see also* AP Ex. 3, at 1[14] (resolution of American Medical Association House of Delegates noting the DSM description of GID as "a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering" that "if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death").

[14] American Medical Association House of Delegates, *Resolution 122 (A-08)*, *Removing Financial Barriers to Care for Transgender Patients* (2008).

We conclude that to the extent the NCD was based on concerns expressed in the NCD record about problems diagnosing transsexualism, that concern is unreasonable based on the new evidence.

C. The new evidence indicates that transsexual surgery is safe.[15]

The 1981 report stated that transsexual surgery "cannot be considered safe because of the high complication rates." NCD Record at 18. The 1981 report identified surgical complications including "rectovaginal fistulas, perineal abscesses, introital and deep vaginal stenosis, and vaginal shortening" in male-to-female (MF) patients, and "rejection of the testicular implants, scrotal fusion, and phalloplasty infections" in female-to-male (FM) patients, and states that "[m]ultiple complications for individual patients and secondary surgeries to correct complications or to improve on undesirable results are not uncommon." *Id.* at 15 (citations omitted). The AP argues that "advancements in surgical techniques have dramatically reduced the risk of complications from sex reassignment surgery and the rates of serious complications from such surgeries are low" and that the studies cited in the 1981 report "evaluated outdated surgical techniques that have been replaced with improved, safer procedures." AP Statement at 7, 10. The new evidence supports the AP.

Expert witness Katherine Hsiao, M.D., testified that hysterectomies and mastectomies are common procedures used to treat gender GID in transgender men (FM) and "are routinely performed in other contexts, such as in cases of breast cancer, ovarian cancer, uterine cancer and/or cervical cancer . . . ." Hsiao Decl. at ¶ 11. These procedures, she stated, "have low rates of complications" and are "generally identical whether performed on transgender men to treat gender dysphoria or to treat women for these other conditions."[16] *Id.* Dr. Hsiao also stated that "insurance companies routinely cover the costs associated" with hysterectomies. *Id.* Dr. Hsiao testified that based on her own practice of providing surgery to transgender men, "gender affirming surgeries for transgender men are extremely safe and have very low rates of serious complications,"

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[15] We are unable to discuss in the space of this decision all of the new evidence and see no need to do so since it is all unchallenged. However, we find nothing in the new evidence not discussed that would alter our conclusion that the NCD is invalid, at least absent argument or counter-evidence from CMS. We have attached to this decision an Overview of the Scientific Literature in the New Evidence.

[16] Dr. Hsiao testified without contradiction that a "serious complication" of surgery–

> is generally understood among surgeons to include death, conditions requiring an unplanned admission to the Intensive Care Unit or unplanned readmission to the hospital within 30 days, severe hemorrhage requiring transfusion of several units of blood product, permanent disability, an intraoperative injury requiring an unplanned intervention during the surgical procedure, permanent brain damage, or cardiac arrest.

Hsiao Decl. at ¶ 9.

that she has performed hysterectomies for transgender men for the past ten years and that those procedures "are generally identical to the ones I perform on women to treat early cancer or other conditions." *Id.* at ¶ 20. Dr. Hsiao reports having "typically performed multiple obstetrical, gynecologic, or other pelvic surgeries every week, including but not limited to hysterectomies and other advanced pelvic surgeries targeting the reproductive system and adjacent organs . . . ." *Id.* at ¶ 6. Dr. Hsiao's declaration and CV indicate that she is certified by the American Board of Obstetrics and Gynecology, is the chief of the division of gynecology and the director of Ob/Gyn resident education at a California medical center and an assistant clinical professor in the department of obstetrics, gynecology and reproductive medicine at the University of California at San Francisco. *Id.* at ¶¶ 3-6; CV.

Dr. Hsiao further stated, regarding MF transsexual surgery, that she has been part of a surgical team that performed surgery to create a neovagina in women born with a congenital "complete or partial absence of a vagina, cervix, and uterus," a condition called Mayer-Rokitansky-Kuster-Hauser syndrome, or MRKH. Hsiao Decl. at ¶ 12. She stated that this procedure has "a low rate of complications," and that the associated surgical costs are, in her experience, "routinely cover[ed]" by insurance companies for women born with MRKH. She stated that while women with MRKH "can never have biological children … the role of surgery is essential to affirm their gender identity and to align their anatomy with that identity." *Id.*

Dr. Ettner stated that "[t]here is no scientific or medical basis" for the NCD's statement that sex reassignment surgery has not been proven safe and has a high rate of serious complications; that the "[r]ates of complications during and after sex reassignment surgery are relatively low, and most complications are minor;" and that the risk of complications "has, moreover, been dramatically reduced since 1985." Ettner Decl. at ¶¶ 32, 34. Dr. Ettner testified that during eight years at the Chicago Gender Clinic she "regularly consulted with our surgeon" and is "aware of only two major surgical complications, both of which were immediately repaired." *Id.* at ¶ 36. She stated that the clinic "as a whole has a 12 percent complication rate for genital surgery" and that "the vast majority of those complications [were] minor, all were easily corrected, and none involved surgical site infection or readmission." *Id.* Dr. Ettner stated the 1981 report's discussion of surgical complication rates was "outdated and irrelevant based on current medical practices and procedures." Ettner Supp. Decl. at ¶ 9. In particular, she stated that one of the studies cited in the 1981 report's discussion of complications (Laub & Fisk 1974) reflected the use of a MF surgical technique that "led to unacceptably high rates of fistulae and other complications" and was later abandoned by the study's authors. *Id.* at ¶ 10.

Another of the AP's expert witnesses, Marci L. Bowers, M.D., stated in her notarized letter that in her experience of performing gender-related surgeries, transsexual surgery "does not have a higher rate of complication than any other surgery, and in fact has very

few complications, which are mainly minor in nature." Bowers Letter at 1 (Mar. 5, 2013), Att. to AP Statement. Dr. Bowers stated that she performs approximately 220 gender-related surgeries annually and has performed over 1000 "Male to Female Gender Corrective Surgeries." *Id.* Her CV indicates that she has served as the Chair of the Department of Obstetrics and Gynecology at the Swedish (Providence) Medical Center in Seattle.

The fourth expert witness, Sherman N. Leis, M.D., stated that he personally "perform[s] several gender reassignment procedures each week" and has "seen only relatively minor complications which are easily treated" and has "thus far seen no life threatening complications from any of the transgender surgeries" he has performed. Leis Letter at 2 (Feb. 28, 2013), Att. to AP Statement. Dr. Leis's letter and CV indicate that he is Board-certified in plastic and reconstructive surgery and in general surgery. *Id.* at 1.

The testimony of Drs. Ettner and Hsiao is based on studies as well as personal experience. Dr. Hsiao testified that she reviewed five studies in the AP exhibits "that include complication rate data and information for gender affirming surgeries performed in recent years" and that "[n]one of these five studies reported high rates of serious complications." Hsiao Decl. at ¶¶ 13-14, citing studies at AP Exs. 2, 9, 14, 21, 28. She stated that "almost all of the complications listed in these studies, such as urinary incontinence or retention, stenosis or stricture, bleeding, recto-vaginal fistula, and partial necrosis, are not specific to sex reassignment surgeries, but rather are known potential side effects of any type of urogenital surgery which are covered by Medicare." *Id.* at ¶ 15. She further testified that "every complication tracked in [Jarolim, et al. (2009)] for instance, falls into this category and none of them are serious;" that "[t]he Spehr (2007) study includes similar types of complications at very low rates;" and that "none of the complications listed in Lawrence (2006) are serious and many of them are consistent with what would be potential, expected outcomes for any urogenital surgery." *Id.* at 15-17, citing studies at AP Exs. 14,[17] 21,[18] 28.[19] She also stated that of the four "potentially serious" complications noted in the Amend (2013) study of 24 MF patients, none "were serious as that term is generally understood." *Id.* at ¶ 14, citing study at AP Ex. 2.[20]

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[17] Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009).

[18] Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006).

[19] Christiane Spehr, *Male-to-Female Sex Reassignment Surgery in Transsexuals*, 10 Int'l J. Transgenderism 25-37 (2007).

[20] Bastian Amend, et al., *Surgical Reconstruction for Male-to-Female Sex Reassignment*, 64 Eur. Urol. 1-9 (2013).

Dr. Hsiao further stated that Eldh et al. (1997) compared complication rates for surgeries performed before and after 1986 and showed that "[n]early all of the surgical complication rates decreased significantly over time." Hsiao Decl. at ¶ 18, citing study at AP Ex. 9.[21] Dr. Hsiao stated that "fistulas, in particular, which are a risk of many urogenital surgeries, decreased from 18 percent in surgeries before 1986 to only 1 percent between 1986 and 1995," and that "the only fistula that occurred after 1985 'closed spontaneously,' meaning without the need for any medical intervention." *Id.* Eldh, Dr. Hsiao stated, showed that "[t]here is not a high rate of serious complications in any of the surgeries performed after 1986" and she noted that "there have been nearly 20 years of additional surgical progress since the last surgery tracked." *Id.*

Dr. Ettner cited the same five studies as showing that surgical outcomes were "far superior" after 1985 due to "improvements in technique, shortened hospital stays and improvements in postoperative care;" that significant surgical complications were uncommon; that only a low percentage of patients experienced complications, which were successfully resolved; and that "the complication rate is low and most complications can be overcome by adequate correctional interventions." Ettner Decl. at ¶¶ 34-35.

We find no reason to discount the opinions of these experts or their representations regarding the findings in the studies they cite. We have conducted our own review of the studies cited by Dr. Hsiao and Dr. Ettner and find them consistent with these opinions and representations. We note, for example, that Eldh, which divided the study group into those operated on before 1986 and those operated on from 1986–1995, made findings tending to support these expert opinions. The Eldh study states:

> After 1985 the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment. Total time spent in hospital decreased dramatically after 1985 because the number of procedures was less and the rate of early and late postoperative complications dropped. Haemorrhage and haematoma were common in both groups, predominantly originating from the spongious tissue of the urethra. Infections occurred less often in the late group perhaps as a result of peroperative antibiotic prophylaxis. Serious complications like fistula formation and partial flap necrosis were rare after 1985, though they were common before then. The reason for the lower fistula rate in the later group may be ascribed to better anatomical knowledge of this region and a more precise surgical technique. There was only one rectovaginal fistula after 1985 and this fistula closed spontaneously.

[21] Jan Eldh, *et al.*, *Long-Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997).

AP Ex. 9, at 44. Dr. Hsiao stated that those findings are "consistent with what I would expect to find when comparing surgeries, and surgical techniques, over a long period of time." Hsiao Decl. at ¶ 18; *see also* WPATH Br. at 9-10 (citing Eldh and stating that "while early sex reassignment surgeries were sometimes accompanied by serious complications like fistulas or necrotic tissue, the rate of such complications has dropped dramatically with the advent of more sophisticated surgical techniques, among other reasons").

We conclude that the AP has shown that the NCD's statement that transsexual surgery is unsafe and has a high rate of complications is not reasonable in light of the evolution of surgical techniques and the studies of outcomes discussed in the unchallenged new evidence presented here.

D. The new evidence indicates that transsexual surgery is an effective treatment option in appropriate cases.[22]

1. The expert testimony and studies on which the experts rely support the surgery's effectiveness.

The AP argues that studies conducted after the 1981 report was issued confirm that transsexual surgery is an effective treatment for persons with severe gender dysphoria, and the expert testimony and studies support that argument. AP Statement at 7-8.

Dr. Ettner testified that "[b]ased on decades of extensive scientific and clinical research, the medical community has reached the consensus that altering a transsexual individual's primary and secondary sex characteristics is a safe and effective treatment for persons with severe Gender Identity Disorder." Ettner Decl. at ¶ 13.[23] With regard to effectiveness in particular, Dr. Ettner testified that "more than three decades of research confirms that sex reassignment surgery is therapeutic and therefore an effective treatment for Gender Identity Disorder" and that "for many patients with severe Gender Identity

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[22] We use the term "appropriate cases" because we do not read the new evidence as necessarily stating that transsexual surgery is appropriate in all cases of transsexualism, and our conclusion that the NCD's blanket preclusion of Medicare coverage for transsexual surgery is invalid does not require a finding to that effect. However, it is worth noting that WPATH has developed, in its standards of care, criteria for the use of different transsexual surgical procedures. *See, e.g.*, WPATH "[c]riteria for hysterectomy and salpingooophorectomy in [FM] patients and for orchiectomy in [MF] patients." AP Ex. 7, at 202 (E. Coleman, et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7, 13 Int'l J. Transgenderism 165–232 (2011)).

[23] Dr. Ettner in her declaration focuses on genital surgery for the male-to-female (MF) transsexual. *See* Ettner Decl. at ¶ 8. Dr. Hsiao's testimony addressed procedures performed on FM patients. Hsiao Decl. at ¶¶ 7, 11, 20-21.

Disorder, sex reassignment surgery is the only effective treatment." *Id.* at ¶ 19. She concluded that "[t]he NCD's determination regarding efficacy is not reasonably supported by scientific or clinical evidence, or standards of professional practice, and fails to take into account the robust body of research establishing that surgery relieves, and very often completely eliminates, gender dysphoria." *Id.* at ¶ 31.

Dr. Bowers stated that "[m]any patients report a dramatic improvement in mental health following surgery, and patients have been able to become productive members of society, no longer disabled with severe depression and gender dysphoria." Bowers Letter at 1. She concluded that "Gender Corrective Surgery has been shown to be a life-saving procedure, and is unequivocally medically necessary." *Id.* Dr. Leis stated that "[m]edical literature reports a dramatic drop in the incidence of depression and suicide attempt[s] by individuals who have undergone gender reassignment, indicating that many lives have been saved because of this surgery," that "there is a very low incidence of 'regret'" of "only about 1% of patients who have had gender reassignment surgery" and that "I personally have never had a single patient who has regretted having this surgery." Leis Letter at 2.

Dr. Ettner cited 20 studies published between 1987 and 2010 as showing the effectiveness of transsexual surgery. Ettner Decl. at ¶¶ 20-26, 28-30. She emphasized three studies, two of which were published in 1998 and 2007 and analyze other studies of the treatment of transsexuals published during the years 1961 to 1991 and 1990 to 2007, respectively. *Id.* at ¶¶ 20-22, citing studies at AP Exs. 10, 25, 27; *see also* WPATH Br. at 7-8 (discussing the same three studies). The 1998 study (Pfafflin & Junge) reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery" including more than 70 individual studies and eight published reviews from four continents. AP Ex. 25 at unnumbered page 1.[24] As "general results," the researchers in the 1998 study stated that the studies they reviewed concluded "that gender reassigning treatments are effective," that positive, desired results outweigh the negative or non-desired effects, and that "[p]robably the most important change that is found in most research is the increase of subjective satisfaction [which] contrasts markedly to the subjectively unsatisfactory start position of the patients." *Id.* at 45, 49. The study's summary, which it qualified as a "simplification," stated that the studies reviewed show that "[i]n over 80 qualitatively different case studies and reviews from 12 countries, it has been demonstrated during the last 30 years that the treatment that includes the whole process of gender reassignment is effective." *Id.* at 66. The summary stated that all "follow-up studies mostly found the desired effects" the most important of

[24] Friedemann Pfafflin & Astrid Junge, *Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991* (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992) (http://web.archive.org/web/20061218132346/http://www.symposion.com/ijt/pfaefflin/1000.htm, accessed May 29, 2014).

which the patients felt were "the lessening of suffering" and "desired changes in the areas of partnership and sexual experience, mental stability and socio-economic functioning level." *Id.* at 66-67.

The 2007 study, Gijs & Brewaeys, which examined the results of 18 studies published between 1990 and 2006, states that sex reassignment "is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals" and that "96% of the persons who underwent [surgery] were satisfied and regret was rare." AP Ex. 10, at 215, cited in Ettner Decl. at ¶ 22, WPATH Br. at 7.[25] Two of the reviewed studies showed that "[s]uicidality was significantly reduced postoperatively" and that in MF patients there were no suicide attempts after surgery as opposed to three attempts before surgery. AP Ex. 10, at 188, 192.

Dr. Ettner and WPATH also cited what Dr. Ettner described as "a large-scale prospective study" finding "that after surgery there was 'a virtual absence of gender dysphoria' in the cohort and that the 'results substantiate previous conclusions that sex reassignment is effective.'" Ettner Decl. at ¶ 21, citing Smith et al. (2005), AP Ex. 27;[26] WPATH Br. at 8. Dr. Ettner concluded that Smith et al. and other studies have, variously, "shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, sex reassignment surgery improves virtually every facet of a patient's life," including "satisfaction with interpersonal relationships and improved social functioning," "improvement in self-image and satisfaction with body and physical appearance," and "greater acceptance and integration into the family[.]" Ettner Decl. at ¶ 24, citing studies at AP Exs. 1, 12, 15, 19, 22, 26, 27, 30. She also cited nine studies as having "shown that surgery improves patients' abilities to initiate and maintain intimate relationships." *Id.* at ¶ 25, citing studies at AP Exs. 8, 13, 14, 16, 20-22, 26, 27.

Based on our own review of the cited studies, we find no reason to question the expert testimony about them. In general, the studies included interviewing post-operative patients with a variety of surveys or questionnaires to assess changes in different aspects of their lives and psychological symptoms following surgery. The studies also generally used statistical techniques to assess the results. The studies were conducted in countries including the United States, Canada, Sweden, the Czech Republic, Israel, Brazil, The Netherlands, and Belgium.

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[25] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges,* 18 Ann. Rev. Sex Res. 178-224 (2007).

[26] Yolanda L.S. Smith et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals,* 35 Psychol. Med. 89-99 (2005).

We note that these studies are scientific writings and do not make sweeping pronouncements or claim discoveries beyond possible doubt. Indeed, the authors sometimes qualify the results and caution against drawing overly broad and simplistic conclusions. *See, e.g.*, AP Ex. 25, at 66 (Pfafflin & Junge, qualifying the study's summary of its conclusion as a simplification). This, in our view, enhances their facial credibility. Nonetheless, even keeping in mind the possible limitations of these studies, they support the AP's position that transsexual surgery has gained broad acceptance in the medical community.

2. *The 1981 report's expressed concern about an alleged lack of controlled, long-term studies is not reasonable in light of the new evidence.*

The 1981 report summarized the findings of nine studies on "[t]he result or outcome of" transsexual surgery. NCD record at 15-18. With respect to those studies, the report stated that "surgical complications are frequent, and a very small number of post-surgical suicides and psychotic breakdowns are reported." *Id.* at 17-18. However, the report also acknowledged that eight of those nine studies "report that most transsexuals show improved adjustment on a variety of criteria after sex reassignment surgery, and that "[i]n all of these studies the large majority of those who received surgery report that they are personally satisfied with the change[.]" NCD Record at 17. Notwithstanding its discussion of these studies, the 1981 report (and the NCD) cited an alleged "lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism" as a ground for finding the procedures "experimental." *Id.* at 19. The 1981 report did not define "long term" for the purpose of assigning weight to study results and the NCD record provided no clarification of that phrase. The 1981 report noted "post-operative followup" and "followup" times for eight of the nine studies on the outcomes of surgery, with "average," "mean" or "median" periods ranging from 25 months to over eight years, and individual periods from three months to 13 years. NCD Record at 15-17. If these studies do not qualify as acceptable long-term studies, the basis for such a conclusion is not adequately explained in the NCD record.

Even assuming the studies cited in the 1981 report could be viewed as not sufficiently "long-term," Dr. Ettner stated that "there are numerous long-term follow-up studies on surgical treatment demonstrating that surgeries are effective and have low complication rates" and, as discussed above, her testimony cited some of those studies. Ettner Decl. at ¶ 26. CMS does not challenge this statement, and we find no reason to question it. We note that the participants in one study Dr. Ettner cited had a mean interval since

vaginoplasty of 75.46 months. AP Ex. 30, at 754.[27] We also note that the 18 studies published between 1990 and 2006 and encompassing 807 MF and FM patients analyzed in Gijs & Brewaeys (2007) had mean follow-up durations ranging from six months to as long as (in one study) 168 months. AP Ex. 10, at 186-87.[28] Additionally, two studies Dr. Ettner cited appear to be long term in that they studied patients who had undergone surgery during periods of 14 and 20 years, respectively. AP Exs. 13,[29] 29.[30] Those studies reported favorable overall results.

Dr. Ettner also testified that two studies from 1987 and 1990 used control groups and found improved psychosocial outcomes in surgery patients. Ettner Decl. at ¶¶ 28-30. In the 1990 study, she stated, MF patients were "matched for family and psychiatric histories and severity of the [GID] diagnosis" and "randomly assigned either to immediately undergo surgery, or be placed on a waiting list for two years." *Id.* at ¶ 29, citing study at AP Ex. 23.[31] The study found that patients who underwent surgery "demonstrated dramatically improved psychosocial outcomes, compared to the still-waiting controls" and "were more active socially and had significantly fewer psychiatric symptoms." *Id.*; *see also* WPATH Br. at 8 (study found "comparative improvements in neurotic symptoms and social activity for the group receiving surgery"). Dr. Ettner described the 1990 study as the "best example of a well-controlled investigation." Ettner Decl. at ¶ 29. Dr. Ettner also described a 1987 study comparing transsexuals who had undergone surgery with "those who had not, but were otherwise matched (control group)" as finding that "the patients who underwent surgery were better adjusted psychosocially, had improved financial circumstances, and reported increased satisfaction with sexual experiences, as compared to the unoperated group." *Id.* at ¶ 30, citing study at AP Ex. 17.[32]

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[27] Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009).

[28] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges,* 18 Ann. Rev. Sex Res. 178-224 (2007).

[29] Ciro Imbimbo, M.D. Ph.D., et al., *A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals*, 6 J. Sex. Med. 2736-45 (2009).

[30] Svetlana Vujovic, M.D. Ph.D., *et al.*, *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009).

[31] Charles Mate-Kole, et al., *A Controlled Study of Psychological and Social Change After Surgical Gender Reassignment in Selected Male Transsexuals*, 157 Brit. J. Psychiatry 261-64 (1990).

[32] G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study*, 16 Archives of Sexual Behavior 511-22 (1987).

Nothing in the record puts into question the authoritativeness of the studies cited in the new evidence based on methodology (or any other ground). Even if questions about methodology had been raised, we would be hard pressed to find that this alone would justify our not crediting the new evidence that transsexual surgery is effective and safe. This is particularly true since the 1981 report itself suggested it might be impossible to find the kind of adequate control groups needed to assuage this criticism. *See* NCD Record at 18 (stating the need for adequate control groups and stating "perhaps this is impossible."). We note that in the local coverage determination (LCD) context, CMS guidance for contractors states that the determinations "shall be based on the strongest evidence available." CMS Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.7.1.[33] While the guidance states a "preference" for "[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies . . .," it also includes as evidence meeting that standard, "[g]eneral acceptance by the medical community (standard of practice), as supported by sound medical evidence . . . ."[34] *Id.* In *LCD Complaint: Homeopathic Med. & Transfer Factor*, DAB No. 2315 (2010), the Board relied on that guidance when rejecting the argument that a certain type of controlled study was the sole basis on which a determination of medical necessity could be supported. The Board stated, "[a]s the [CMS guidance] explains, general acceptance in the medical community may be sufficient if it has scientific support." DAB No. 2315, at 34. While the guidance applies to contractors, who develop LCDs but not NCDs, it is instructive here as representing CMS's determination of the type of evidence that may support Medicare coverage. Regardless of whether the new evidence here meets the first option for meeting the evidentiary standard set forth in the guidance (and CMS does not assert that it does not), it clearly meets the second option because it indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism.

Based on the record as a whole, including the new evidence discussed above, we conclude that the AP has shown that transsexual surgery is an effective treatment option for transsexualism in appropriate cases.

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[33] CMS Manuals are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html, accessed May 14, 2014.

[34] The guidance further provides that the "sound medical evidence" supporting this "general acceptance" should be based on "[s]cientific data or research studies published in peer-reviewed medical journals; … [c]onsensus of expert medical opinion (i.e., recognized authorities in the field); or … [m]edical opinion derived from consultations with medical associations or other health care experts." MPIM § 13.7.1.

E. The new evidence indicates that the NCD's rationale for considering the surgery experimental is not valid.

The NCD asserted that transsexual surgery was considered experimental because it had not been shown to be safe and effective.[35] The 1981 report stated that transsexual surgery "must be considered still experimental" because "[t]he safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned." NCD Record at 19. As discussed above, the unchallenged new evidence indicates that transsexual surgery is a safe and effective treatment option for transsexualism in appropriate cases. Accordingly, the NCD's reasons for asserting that transsexual surgery was experimental are no longer valid.

In addition, the new evidence independently indicates that transsexual surgery is not considered experimental in a broader sense relating to its acceptance as a treatment for transsexualism. Dr. Bowers stated that "[m]any thousands of gender corrective surgeries have been performed worldwide for decades, and this treatment is in no way experimental." Bowers Letter at 1. Dr. Hsiao testified that there is "no scientific or medical basis for [the NCD's] description of gender affirming surgeries as 'experimental.'" Hsiao Decl. at ¶ 22. Dr. Hsiao, as noted, stated that some of the procedures involved in transsexual surgery are routinely performed in other contexts, and that surgery to create a neovagina is performed on women born MRKH. Hsiao Decl. at ¶¶ 11, 12; *see* Ettner Supp. Decl. at ¶ 15 ("mastectomies, hysterectomies and salpingo-oophorectomies, which are … excluded from coverage under [the NCD] are performed frequently… when indicated for medical conditions other than gender dysphoria").

Dr. Hsiao cited the "increasing coverage of sex affirming surgeries by private and public medical plans" and the inclusion of those surgeries "in prominent surgical text books" as showing that "gender affirming surgeries … are the standard of care and are not experimental." *Id.* at ¶¶ 23, 24. Dr. Hsiao cited California managed care guidance "clarifying that any attempt 'to exclude insurance coverage of [] transsexual surgery'" would violate California law, and she stated that Vermont, Colorado, Oregon, and Washington, D.C. "have issued similar insurance directives prohibiting discrimination based on gender identity with respect to healthcare policies." *Id.* at ¶ 25, citing Letter No. 12-K: Gender Nondiscrimination Requirements, Calif. Dep't of Managed Health Care

[35] "Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental." NCD Record at 93.

(Apr. 9, 2013), Ex. A to Hsiao Decl.[36] "These events in the private and public sector," Dr. Hsiao stated, "solidify what the medical community has known for years—that gender affirming surgeries to treat gender dysphoria are evidence-based, medically necessary, and the standard of care for these patients." *Id.* at ¶ 26.

Dr. Leis stated that gender reassignment surgery "is not experimental and has been performed thousands of times with surgeons around the world and has been proven to be a medically necessary and successful treatment, saving many lives and significantly improving the lives of those who undergo this surgery." Leis Letter at 2. Dr. Leis also stated that "[m]edical and mental health professionals who are knowledgeable and experienced in this field recognize that counseling or psychotherapy, hormone therapy and genital reassignment surgery are medically necessary treatment modalities for many individuals with [GID]" and that those therapies "are widely accepted treatments for individuals with significant [GID] in the United States and in many other countries." *Id.* at 1. Dr. Leis also pointed to the acceptance of transsexual surgery procedures "as standard therapy by leading medical and mental health organizations" including the American Medical Association, the National Association of Social Workers, the American Psychological Association, the American Psychiatric Association, "and experts in the field belonging to" WPATH. *Id.* at 2.

HRC stated that its "Corporate Equality Index" annually surveys the "LGBT [lesbian, gay, bisexual and transgender] workplace policies" of "the Fortune 1000 list of the largest publicly traded companies along with American Lawyer Magazine's top 200 revenue-grossing law firms" and considers "whether these organizations afford transgender-inclusive health care options through at least one firm-wide plan that covers surgical procedures." HRC Br. at 1, 11-12. HRC stated that in 2002, "zero percent of the rated companies had such plans" but "by 2008, nineteen percent met this criterion, and by 2013, forty-two percent of companies expressly covered" care related to gender reassignment. *Id.* citing HRC Ex. 30, at 28.[37]

Dr. Bowers, Dr. Hsiao and Dr. Ettner cited acceptance of the WPATH standards of care, which were first published in 1979 and last revised in 2011, as evidence that transsexual surgery is not experimental. Bowers Letter at 1; Hsiao Decl. at ¶ 22; Ettner Decl. at ¶¶ 38, 39; AP Ex. 7, at 165; *see also* AP Ex. 3 (AMA resolution stating that "[h]ealth experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition"). The new evidence indicates that

[36] http://www.dmhc.ca.gov/library/reports/news/dl12k.pdf, accessed May 14, 2014.

[37] HRC Corporate Quality Index (2013), available at http://www.hrc.org/corporate-equality-index, accessed April 25, 2014.

the WPATH standards of care have attained widespread acceptance.[38] S*ee* Hsiao Decl. at ¶ 22 ("the WPATH established standards of care for patients with gender dysphoria … have been endorsed by the American Medical Association, the Endocrine Society, the American Psychological Association, and the American College of Obstetricians and Gynecologists"); AP Ex. 3 (AMA resolution stating that WPATH is "the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders" and that its "internationally accepted Standards of Care for providing medical treatment for people with GID … are recognized within the medical community to be the standard of care for treating people with GID"). Federal courts have recognized the acceptance of the WPATH standards of care. *See, e.g.*, *De'lonta v. Johnson*, 708 F.3d 520, at 522-23 (4th Cir. 2013) (WPATH standards of care "are the generally accepted protocols for the treatment of GID"); *Glenn v. Brumby*, 724 F. Supp. 2d 1284, at 1289 n.4 (N.D. Ga. 2010) ("there is sufficient evidence that statements of WPATH are accepted in the medical community")."[39] The acceptance of the WPATH standards of care also suggests that transsexual surgery is no longer considered experimental.

In its amicus brief, WPATH cited a 2007 study that examined the results of 18 studies published between 1990 and 2006 as showing "that [sex reassignment surgery] can no longer be considered an experimental treatment" and that "it [has] bec[o]me the dominant treatment for transsexuality and the *only* treatment that has been evaluated empirically." WPATH Br. at 7-8, citing AP Ex. 10, at 214-15.[40]

We note that in addition to stating that transsexual surgery was experimental, the NCD and the 1981 report stated that transsexual surgery was "controversial." NCD Record at 18 (1981 report stating that "[o]ver and above the medical and scientific issues, it would also appear that transsexual surgery is controversial in our society"). The AP and the new evidence dispute the relevance of this statement. The AP objected that this point relies on two "polemics" that are "are either completely unscientific or fall far outside the scientific mainstream," and Dr. Ettner stated that the views expressed therein "fall far outside the mainstream psychological, psychiatric, and medical professional consensus,

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[38] WPATH was "formerly the Harry Benjamin International Gender Dysphoria Association." Ettner Decl. at ¶ 6. Harry Benjamin, M.D. "was an endocrinologist who in conjunction with mental health professionals in New York did pioneering work in the study of transsexualism." *O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, 37 n.8 (2010). The 1981 report cites a 1966 study by Dr. Benjamin finding a positive outcome from MF transsexual surgery as "perhaps the first report" on transsexual surgery "in the literature." NCD Record at 15, 21.

[39] The general acceptance of a set of standards of care for the treatment of transsexuals appears to render invalid one of the 1981 report criticisms of the studies it discussed, that "therapeutic techniques are not standardized." NCD Record at 18.

[40] Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges,* 18 Ann. Rev. Sex Res. 178-224 (2007).

and call into question the objective reasonableness of the NCD." AP Statement at 15-16; Ettner Supp. Decl. at ¶¶ 17-18. CMS has not asserted that the Board's decision may be based on factors "over and above the medical and scientific issues" involved. Considerations of social acceptability (or nonacceptability) of medical procedures appear on their face to be antithetical to Medicare's "medical necessity" inquiry, which is based in science, and such considerations do not enter into our decision that the NCD is not valid.

For the reasons stated above, we conclude that citing the alleged "experimental" nature of transsexual surgery as a basis for noncoverage of all transsexual surgery is not reasonable in light of the unchallenged new evidence and contributes to our conclusion that the NCD is not valid.

Conclusion

For the reasons explained above, we conclude that the AP has shown that NCD 140.3 is not valid under the reasonableness standard.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member

ATTACHMENT TO DECISION NO. 2576

Overview of the Scientific Literature in the New Evidence

We provide below brief summaries of key findings in some of the studies submitted and reviewed by the Board as new evidence. The key findings in the remaining studies reviewed by the Board (also as new evidence) do not differ in any way material to our decision.

Jan Eldh, et al., *Long Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997), AP Ex. 9. This study was a "long-term follow up of 136 patients operated on for sex reassignment … to evaluate the surgical outcome" that divided MF and FM patients into "two groups according to the surgical technique: those operated on before 1986 and those operated on from 1986–1995." The study found that after 1985 "the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment," that "[m]odern surgical techniques can give good aesthetic and functional results" and that "[p]ersonal and social instability before operation correlated with an unsatisfactory outcome of sex reassignment." *Id.* at 39, 44, 45.

Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges,* 18 Ann. Rev. Sex Res. 178-224 (2007), AP Ex. 10. This study examined results of 18 international studies published between 1990 and 2006 that reported follow-up data of at least one year from 807 persons who had undergone sex reassignment surgery (193 FM, 614 MF). The purpose of this study was to update and assess the current validity of a conclusion in a 1990 article (based itself on review of 11 studies following post-operation) that transsexual surgery is an effective treatment for the alleviation of gender disorder in adults. This study concluded that "[d]espite methodological shortcomings of many of the studies . . . SRS is an effective treatment for transsexualism and the only treatment that has been evaluated empirically with large clinical case series" and that the "conclusion that SR [sex reassignment] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: 96% of the persons who underwent SRS were satisfied and regret was rare." The authors noted that the methodologies and designs of later studies were improved but that true randomized control studies are not feasible, and might be unethical for SRS. *Id.* at 178, 185, 215-16.

Ciro Imbimbo, M.D. Ph.D., et al., *A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals*, 6 J. Sex. Med. 2736-45 (2009), AP Ex. 13. This study's aim was "to arrive at a clinical and psychosocial profile of male-to-female transsexuals in Italy through analysis of their personal and clinical experience and evaluation of their postsurgical satisfaction levels SRS." From January 1992 to September 2006, 163 MF patients who had undergone SRS were asked to complete

patient satisfaction questionnaires. The study concluded that the "relatively high satisfaction level" was the result of a combination of "competent surgical skills, a well-conducted preoperative preparation program, and adequate postoperative counseling . . . ." Although postoperative pain and required revision surgeries were reported, the study found that 94% were satisfied with their post-surgical status and did not report regret. *Id.* at 2736, 2740, 2743.

Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009), AP Ex. 14. This study aimed "[t]o evaluate the results of surgical reassignment of genitalia in male-to-female transsexuals" by measuring "[s]exual functions and complications 3 months after surgery." The study followed 134 patients who had undergone surgical procedures between 1992 and 2008 and described the evolution in surgical techniques since the 1950s. Although the study noted potential complications and risks specific to SRS ("such as impairment of urinary continence, fecal continence, intestinal fistula, urinary fistula, and necrosis of the skin graft"), it concluded that "[s]urgical conversion of the genitalia is a safe and important phase of the treatment of male-to-female transsexuals." It also concluded that "[a]n increasing number of patients undergo this treatment because of the extensive progress in surgery involving the genitals and urethra" and that "[f]or male transsexuals, surgery can provide a cosmetically acceptable imitation of female genitals that enables coitus with orgasm." *Id.* at 1635-36,1642-43.

Annika Johansson, et al., *A Five-Year Follow-Up Study of Swedish Adults with Gender Identity Disorder,* 39 Arch. Sex. Behav. 1429-37 (2010), AP Ex. 15. This study evaluated from the perspective of both clinicians and patients the outcome of sex reassignment of "42 [MF and FM] transsexuals [who] completed a follow-up assessment after 5 or more years in the process or 2 or more years after completed sex reassignment surgery." It found that "the outcome was very encouraging from both perspectives … with almost 90% enjoying a stable or improved life situation at follow-up and only six out of 42 (according to the clinician) with a less favorable outcome." *Id.* at 1429, 1436.

G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study,* 16 Archives of Sexual Behavior 511-22 (1987), AP Ex. 17. This single-clinic study compared 26 transsexuals who sought but did not undergo surgery with 32 who did; psychosocial adjustment of those who delayed surgery did not improve from the time of diagnosis to follow-up while statistically significant positive changes in gender role, sexual, and socioeconomic adjustment were seen in transsexuals who had had surgery. *Id.* at 511, 517-19, 521.

Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006), AP Ex. 21. This study "examined preoperative preparations, complications, and physical and

functional outcomes of [MF SRS] based on reports by 232 patients, all of whom underwent penile-inversion vaginoplasty and sensate clitoroplasty, performed by one surgeon using a consistent technique," who were surveyed a mean of three years after surgery. The study found that "[r]eports of significant surgical complications were uncommon," although one third had urinary stream problems, and that "[o[n average, participants expressed high levels of satisfaction with nearly all of the specific physical and functional outcomes of SRS." *Id.* at 717, 719, 724.

Maria Inês Lobato, et al., *Follow-Up of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort,* 35 Arch. Sex. Behav. 711-15 (2006), AP Ex. 22. This small study examined the "impact of sex reassignment surgery on satisfaction with sexual experience, partnerships, and relationship with family members in … 19 patients who received sex reassignment between 2000 and 2004." The results "indicate[d] that SRS had a positive effect on different dimensions of the patients' lives in all three aspects analyzed: sexual relationships, partnerships, and family relationships." *Id.* at 711-12, 714.

Charles Mate-Kole, et al., *A Controlled Study of Psychological and Social Change after Surgical Gender Reassignment in Selected Male Transsexuals*, 157 Brit. J. Psychiatry 261-64 (1990), AP Ex. 23. This study reviewed 40 patients accepted for gender reassignment surgery, randomly assigned to have surgery early or later such that only half had had surgery by the time of a follow-up two years later. The study found that "[a]lthough the groups were similar initially, significant differences between them emerged at follow-up . . . ." Patients who received surgery were "seen to improve significantly as far as neurotic symptoms are concerned and to become more socially active" in comparison with the patients who had not yet received surgery. *Id.* at 261, 264.

Friedemann Pfafflin & Astrid Junge, *Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991* (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992), AP Ex. 25. This overview was completed in 1992 and published in English in 1998. It reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery," including "more than 70 individual studies and eight published reviews from four continents." In general, more frequent and severe complications were found in the earlier years covered than in later reports. The overview concluded that "[s]ex reassignment, properly indicated and performed, has proven to be a valuable tool in the treatment of individuals with transgenderism," that "gender reassigning treatments are effective" and that "the treatment that includes the whole process of gender reassignment is effective." *Id.* at unnumbered pages 1, 45, 66-67.

Yolanda L.S. Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals,* 35 Psychol. Med. 89-99 (2005), AP Ex. 27. This study evaluated "outcomes of sex reassignment, potential differences between subgroups

of transsexuals, and predictors of treatment course and outcome" in 162 adults (104 MF, 58 FM). The study found that "[a]fter treatment the group was no longer gender dysphoric," had "improved in important areas of function, that 1-4 years after surgery, SR appeared therapeutic and beneficial . . . [and that] the vast majority expressed no regrets about their SR." The study further concluded "that sex reassignment is effective" but that "clinicians need to be alert for non-homosexual male-to-females with unfavourable psychological functioning and physical appearance and inconsistent gender dysphoria reports, as these are risk factors for dropping out and poor post-operative results." *Id.* at 89, 91, 96.

Svetlana Vujovic, M.D., Ph.D., et al., *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009), AP Ex. 29. This study [a]imed to "describe a transsexual population seeking sex reassignment treatment in Serbia" by analyzing "data collated over a period of 20 years" from 147 transsexuals "applying for sex reassignment" of whom SRS was performed in 83% of MF and in 77% of MF patients. The study concluded that "in our population, there were no cases who regretted sex reassignment treatment," which was attributed to diagnostic procedures used and the "young [adult] age at which our subjects embarked on treatment." *Id.* at 1018-20, 1022.

Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009), AP Ex. 30. This study [a]imed "[t]o gather information on physical, mental, and sexual well-being, health-promoting behavior and satisfaction with gender-related body features of [49] transsexual women [MF] who had undergone SRS" with mean interval since vaginoplasty of 75.46 months. The study found that "sample … functions well after surgery on a physical, emotional, psychological and social level" and that "[o]nly with respect to sexuality do transsexual women appear to suffer from specific difficulties, especially concerning arousal, lubrication and pain." *Id.* at 752, 754, 759.

TAB 176-34

Pl. Trial Ex. 074

Moving Beyond Change Efforts:

Evidence and Action to Support and Affirm LGBTQI+ Youth

SAMHSA

Substance Abuse and Mental Health Services Administration

Acknowledgment

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Navigating This Report

This report is written for multiple audiences, to include behavioral health providers, pediatric professionals and primary care providers, educators and school professionals, policymakers, and researchers. Families, parents, caregivers, and community leaders may also find it useful.

Two sections of this report are likely to be informative for all readers:

- **Executive Summary**, which synthesizes the key conclusions of the report
- **Statements of Professional Consensus on Beneficial and Harmful Practices with Youth of Diverse Sexual Orientation and Gender Identity**, which provides key scientific and treatment recommendations

Other sections of this report may be more accessible or useful to specific audiences and are noted below.

Behavioral health providers: All sections of this report are relevant to these professionals. Those primarily engaged in practice and treatment might focus on Section 2, which summarizes current research with lesbian, gay, bisexual, transgender, queer, questioning, and intersex youth and other sexual- and gender-diverse children and youth (LGBTQI+ youth). It describes evidence-based approaches to support and affirm LGBTQI+ children and youth. Section 3 includes an overview of laws that impact treatment and makes recommendations for targeted training and expanding treatment access.

Community leaders: Section 3 includes policy actions for those interested in supporting LGBTQI+ child and adolescent behavioral health. Appendix C provides selected resources for families and caregivers and those who work closely with them.

Educators and school professionals: Section 2 includes information on important school interventions this group can implement to improve the behavioral health of LGBTQI+ children and youth. Section 3 identifies vital steps that aim to improve behavioral health of LGBTQI+ children and youth.

Families and caregivers: Material in this report could help parents and caregivers understand and support a child's behavioral health. Some parents may find the information on schools and behavioral health in Section 2 useful when seeking support and treatment for their children. Appendix C provides selected resources for families, caregivers, and those who work closely with them.

Pediatric professionals and primary care providers: Providers may find Section 1 on the evidence regarding sexual orientation and gender identity (SOGI) change efforts useful, as well as the research summary and description of behavioral health treatment interventions (Section 2). Appendix C provides selected resources for families, caregivers, and those who work closely with them.

Policymakers: Section 3 targets policymakers interested in taking concrete steps to improve LGBTQI+ child and youth behavioral health. This section is relevant to federal, state, and local policymakers as well as advocates and behavioral health providers interested in public policy. Some policy professionals may find the entire report helpful as background information.

Researchers: The research summary in Section 2 and areas for future study provide an overview of recent evidence and scientific opportunities. Section 3 contains recommendations for future research initiatives.

A glossary of terms used throughout this report can be found in Appendix B.

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Executive Summary

Like all youth, lesbian, gay, bisexual, transgender, queer, questioning, and intersex youth and other sexual- and gender-diverse children and adolescents (LGBTQI+[] youth) deserve to grow up in supportive environments absent stigma and discrimination that allow them to thrive and achieve their human potential. When seeking behavioral health treatment (both mental health and substance use interventions), these children and adolescents, like their peers, and their families deserve the best evidence-based care from knowledgeable health providers without the risk of harm.

This report, *Moving Beyond Change Efforts: Evidence and Action to Support and Affirm LGBTQI+ Youth*, provides behavioral health providers, researchers, policymakers, and other audiences with current knowledge about LGBTQI+ youth, a comprehensive research overview, and important information on behavioral health concerns within this community. More specifically, the report provides details on helpful and harmful interventions for these populations in clinical, community, family, and school settings. In particular, the report documents that attempts to change an individual's sexual orientation and gender identity (SOGI; pronounced "SO-gee" change efforts) are harmful and should not be provided. Additionally, this report discusses evidence-informed policy options that could improve the overall health and well-being of LGBTQI+ youth.

As the abbreviation LGBTQI+ suggests, this population is not homogenous. It includes individuals with many distinct sexual orientations, gender identities, gender expressions, and variations in sex characteristics. Sexual and gender minorities are also diverse with respect to other identities, including age, race, ethnicity, language, national origin, religion, spirituality, ability, and socioeconomic status.[#]

This report is focused on the experiences and needs of LGBTQI+ children and adolescents up to age 17 years (referred to collectively as "youth"). In this report, the term "child" is used to refer to youth aged 3-11 years and "adolescent" is used to refer to youth aged 12-17 years.

Critically, LGBTQI+ youth experience significant physical and behavioral health inequities. Several factors contribute to these inequities and result in minority stress, which is harmful to behavioral health, including:[1,2,3,4]

- Stigma
- Negative social attitudes
- Systemic barriers in health care for LGBTQI+ people
- Rejection and lack of support from families, caregivers, and communities
- Bullying and harassment, and lack of recognition and support in schools

Lack of appropriately trained behavioral health providers and exposure to harmful efforts that attempt to change sexual orientation and/or

[] Even though the evidence is more limited regarding intersex persons, they are included in the acronym LGBTQI+ except when it would be inappropriate to do so, such as within journal article citations or a formal resource name. Additionally, LGBTQI+ is used interchangeably with "sexual and/or gender minority," and persons of "diverse sexual orientation and/or gender identity," (or similar language) throughout this report.

[#] For information regarding the terms used to describe sexual orientation and gender identity, see "Sexual Orientation and Gender Identity" within Youth.gov https://youth.gov/youth-topics/lgbt.

gender identity compound these challenges. Additionally, some transgender and gender-diverse youth require behavioral health support for their experience of gender dysphoria—that is, psychological distress arising from the incongruence between one's body and gender identity.[5]

The conclusions in this report are based on research and professional consensus statements from experts in behavioral health, research, education, and policy. They strengthen and build on the conclusions of a 2015 report published by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth*, the precursor to this report.[6] An overarching and guiding conclusion of this new report is that SOGI change efforts in children and adolescents are harmful and should never be provided. Although the terms "conversion therapy" and "reparative therapy" are commonly used to describe efforts to repress or change someone's sexual orientation or gender identity, these efforts are not therapeutic, and using these terms reinforce disinformation that sexual- and gender-diverse people need repair or conversion. Efforts to change or suppress a person's sexual orientation or gender identity are grounded in the belief that being LGBTQI+ is abnormal. They are dangerous, discredited, and ineffective practices. Therefore, this report utilizes the term "SOGI Change Efforts" to describe so-called "conversion therapy." Recent studies have linked SOGI change efforts to significant harms, such as increased risk of suicidality and suicide attempts, as well as other negative outcomes including severe psychological distress and depression.[7,8,9,10,11,12,13]

An overarching and guiding conclusion of this report is that SOGI change efforts in children and adolescents are harmful and should never be provided.

Further, these practices are not supported by credible evidence and have been disavowed as harmful by behavioral health experts and scientific professional associations. SOGI change efforts do not align with current scientific

understanding of gender as well as the unfounded concept that being in a sexual or gender minority group or identifying as LGBTQI+ is an abnormal aspect of human development. Most importantly, they put young people at risk of serious harm.

The U.S. Department of Health and Human Services is committed to eliminating health inequities within communities, including the LGBTQI+ population. This report reflects that commitment by moving the focus away from SOGI change efforts and toward ensuring that behavioral health care for LGBTQI+ children and adolescents is safe and reflects the most current scientific evidence. This report also provides a roadmap for action centered on evidence-based care and helpful interventions for clinicians, all providers, educators, families, caregivers, and policymakers to improve the behavioral health of LGBTQI+ youth. Further, this report reflects priorities included in President Biden's June 15, 2022, Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals,[14] and the January 20, 2021, Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation.[15]

Key Findings

This report and its recommendations are based on scientific research distilled into consensus statements by a Subject Matter Expert Consensus Panel (the Panel; see Appendix D for members). After a thorough review of the scientific research; professional health and scientific association statements, guidelines, and reports; and state and national public policies, and in consultation with professionals across a wide range of expertise, the Panel revised and built on key statements from the 2015 report.

The term "evidence-based care" refers to care, practices, or policies that are based on current research evidence, clinical expertise, and expert consensus.

The Panel reaffirmed that:

- Variations in sexual orientation (including identity, behavior, and attraction) and variations in gender (including identity and expression) are part of the normal spectrum of human diversity and do not constitute mental disorders.

Based on recent studies on thousands of individuals who have undergone SOGI change efforts, the Panel concluded that:

- No available research supports the claim that SOGI change efforts are beneficial to children, adolescents, or families.
- Available research indicates that SOGI change efforts are not effective in altering sexual orientation. Further, no available research indicates that change efforts are effective in altering gender identity.
- Available research indicates that SOGI change efforts can cause significant harm.
- SOGI change efforts are inappropriate, ineffective, and harmful practices that should not be provided to children and adolescents.

In the past several years, the research on gender diversity, gender identity, and gender-affirming medical care for children and adolescents has expanded greatly. The Panel found that:

- Gender affirmation, including social transition, and gender-affirming medical care are appropriate and beneficial for many gender minority youth.

Research over the past 20 years has underscored the importance of family and community support to the health of LGBTQI+ youth. Family and community negativity toward sexual diverse sexual orientation and/or gender identity, especially family rejection and school bullying and harassment, can cause harm to the behavioral health of this population. The Panel confirmed that:

- Rejection and lack of social and emotional support from families and caregivers, schools, and communities negatively affects the health of sexual and gender minority youth. Such behaviors can cause harm, particularly family rejection of the youth's sexual and/or gender diversity.

After a comprehensive review of the substantial research assessing the impacts of public policies, the Panel determined that:

- Policies that stigmatize, restrict, or exclude sexual or gender minority youth are harmful to children and adolescents.
- Legal prohibitions on gender-affirming care (including medical treatment) are harmful to LGBTQ+ children and adolescents.

Understanding Sexual Orientation and Gender in Children and Adolescents

Behavioral health providers, parents, schools, policymakers, and communities can best provide support to children, adolescents, and their families and caregivers and improve their behavioral health when they have access to the most current information about sexual orientation, gender identity, and gender expression in youth. The following overview presents the most current understanding, based on scientific evidence of youth sexual orientation, gender identity, and gender expression.

Sexual orientation occurs across a continuum, and same-sex or same-gender attraction and relationships are normal and healthy variations of human sexuality.[16,17] Similarly, a gender identity that differs from assigned sex at birth, as well as a gender expression that is not aligned with usual or expected cultural norms for a particular gender, are normal and healthy variations of human gender identity.[18,19] It is a longstanding finding that being a person of diverse sexual orientation and/or gender identity, or identifying as LGBTQI+, is not pathological.[18,20,21,22,23,24,25]

While many youth have identified with having a diverse sexual orientation in the past, they have not always felt safe enough to share that diversity openly with others.[26,27,28] There is no single developmental trajectory for sexual orientation. Certainty about sexual orientation—e.g., gay/lesbian, bisexual, or straight—increases with age, suggesting "an unfolding of sexual identity during adolescence."[29] Some researchers have found that it has become more common in the 21st century compared to the 20th century for children to self-identify as having a diverse sexual orientation and/or gender identity.[30] What has changed from earlier periods is that youth appear to be publicly acknowledging their sexual orientation earlier as societal attitudes have increasingly become more accepting and open to diverse sexual orientations. Regardless of age, the increase in identifying as an individual of diverse sexual orientation may be tied to the increasing awareness and acceptance of diverse sexual orientations; the expansion of laws, policies, and practices that protect and support individuals regardless of sexual orientation; and an increased willingness and ability among people with diverse sexual orientations to self-identify.[31] Evidence suggests that acceptance of diverse sexual orientations does not make people more likely to identify with a diverse sexual orientation, but rather it increases the likelihood that people feel safer to identify this way publicly.[32,33,34]

Gender development begins in early childhood and continues throughout childhood and adolescence.[35,36] Gender diversity in youth can follow many possible paths. It may emerge as early as a child's preschool years, in late adolescence, or anytime in between.[37,38,39,40] Some gender-diverse children are actively exploring their gender, and there is variation regarding their identity development trajectories and ultimate identity outcomes.[38,39,40] Recent research has found that most gender-diverse children continue to identify as transgender or another gender identity that differs from their sex assigned at birth into adolescence and adulthood.[39,40,41] For those who exhibited diverse gender-typed behavior in childhood, but did not identify as transgender or nonbinary, the majority reported a diverse sexual orientation in adolescence.[42,43] For transgender children who have been supported in their gender identity and gender expression, the vast majority show consistency in their trans identity across time.[40,44]

Some people are born with differences in sex characteristics, such as reproductive anatomy,

chromosomes, or hormones that do not fit typical definitions of male and female. Intersex is an umbrella term used to describe people who can have different gender identities. Individuals with intersex traits may identify as male, female, nonbinary, or a different gender. Intersex individuals may consider themselves transgender if they do not identify with their sex assigned at birth. Like other LGBTQI+ youth, intersex youth experience pervasive stigma and discrimination. While research involving intersex individuals has been limited,[45] the Federal Government has taken steps to reduce this disparity, such as issuing a Request for Information on Promising Practices for Advancing Health Equity for Intersex Individuals in February 2023.[46]

Supportive families and caregivers, peers, and school and community environments are associated with improved psychosocial outcomes for all children and adolescents, and this is especially true for those children and adolescents with minority sexual orientations or gender identities that do not align with their sex assigned at birth.[47,48,49,50,51,52,53] Extensive research indicates that even just one supportive adult, such as a family member, teacher, or mental health provider, can have a positive impact on the mental health of youth of diverse sexual orientation and/or gender identity; such support can reduce adverse mental health impacts including suicide.[49] Additionally, family or caregiver, peer, school, and community support for youth of diverse sexual orientation and/or gender identity promotes better mental health and fewer negative outcomes, and can lead to positive development and emotional resilience.[47,48,49,53]

Behavioral Health: A broad term that includes mental health, resilience, and well-being; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

Behavioral Health Concerns Among LGBTQI+ Youth

LGBTQI+ adolescents face the same developmental milestones that accompany adolescence for all youth. However, unlike adolescents with a cisgender[1] and straight/heterosexual orientation, LGBTQI+ adolescents often must navigate an environment lacking awareness and acceptance of their sexual orientation and/or gender identity. Moreover, they might have to do so without family, community, or societal support, for example, through the child welfare system.

Limited research with sexual minority children indicates that mental health inequities may begin in childhood,[30,54] which may be connected to greater prevalence of discrimination and victimization among sexual minority children.[55,56] As a result of experiencing stigma and discrimination, some youth with diverse sexual orientation and/or gender identity are at increased risk for:

- Psychological distress (e.g., depressive symptoms, anxiety, and behavioral disorders)
- Substance use
- Suicidal ideation and attempts
- Victimization, violence, and homelessness

[1] "Cisgender" is a term that describes individuals whose gender identity is congruent with their sex assigned at birth. Please refer to Appendix B for a glossary of terms.

- Involvement with child welfare services, often stemming from family rejection
- Involvement in juvenile justice programs[57,58,59,60,61,62,63,64,65]

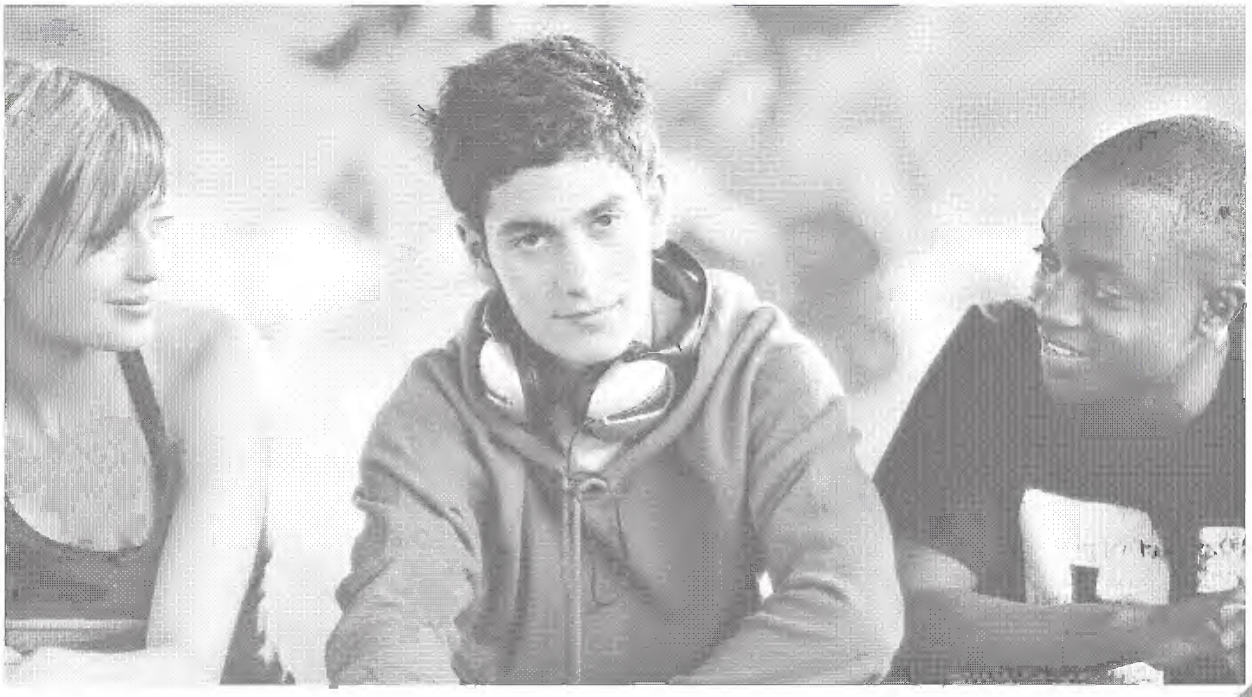
Psychosocial distress is often related to, if not caused by, negative social attitudes or rejection.[66] High levels of parental and caregiver support of youths' sexual orientation and gender identity can mitigate increased risk of behavioral health concerns. For example, transgender and gender-diverse youth with affirming parents and caregivers have similar levels of mental health challenges as their cisgender peers.[67] It is essential to note that youth with diverse sexual orientation and/or gender identity are resilient, and that with sufficient support and access to resources, they can thrive.[68,69]

Some children may experience gender dysphoria, meaning feelings of distress or incongruence between one's gender identity and sex assigned at birth. This distress, rather than the youth's gender diversity, is recognized as a behavioral health concern.[5] For some, the physical changes of adolescence may worsen feelings of gender dysphoria. For others, gender dysphoria or feelings of gender incongruence may begin post-puberty without any childhood history of gender dysphoria or gender diversity.[70]

Developmentally sensitive approaches consider appropriate development of emotional and cognitive capacities, achievement of developmental milestones, and possible emerging or existing behavioral health concerns.

Beneficial Therapeutic Approaches and Interventions With LGBTQI+ Youth

Given scientific findings that SOGI change efforts are harmful and medically inappropriate, the behavioral health approaches below are recommended instead. These approaches are consistent with the Panel's consensus



statements and current research. Several professional and scientific association guidelines recommend these approaches as well.[22,23,24,25,71,72,73,74]

When providing services to children, adolescents, families, and caregivers, appropriate therapeutic approaches include:

- Providing accurate information on sexual orientation, gender identity and expression, and variations in sex characteristics
- Identifying sources of distress, including internalized stigma and minority stress, and working with children, adolescents, families, and caregivers to reduce the distress LGBTQI+ youth experience
- Supporting adaptive coping to improve psychological well-being
- Supporting youth as they learn more about their sexual orientation and gender identity, and supporting families in accessing gender-affirming care for their transgender child when indicated
- Helping children and adolescents navigate their sexual orientation, gender identity, and gender expression within the context of their cultural, religious, and other identities

Interventions should be client-centered, culturally appropriate, and developmentally sensitive. The treatment goal should be to facilitate the best possible level of psychological functioning, rather than identifying with a specific gender or sexual orientation. Appropriate treatment approaches with youth of diverse sexual orientation and/or gender identity should focus on identity development and affirming exploration that allows the child or adolescent the freedom of self-discovery within a context of acceptance and support. It is important to identify the sources of any distress experienced by LGBTQI+ youth and their families and caregivers, and work to reduce this distress.

Working with parents and caregivers is important, as their behaviors and attitudes have significant effects on the mental health and well-being of youth with diverse sexual orientation and/or gender identity. Supportive family, caregivers, community, school, child welfare, and healthcare environments have been shown to positively impact both the short- and long-term health and well-being of LGBTQI+ youth. Families, caregivers, and those working with these youth can benefit from guidance and resources to increase support for sexual- and gender-diverse groups and to reduce stigma and discrimination.

In addition to the appropriate therapeutic approaches described above, social transition is appropriate and beneficial for many transgender and gender-diverse youth.[75,76,77,78] Although professional intervention is not required for youth to take steps in social transition, providers can support families and caregivers to protect youth's safety, ensure emotional, psychological, and social well-being, and help youth and families navigate the potential complexities of exploring and taking steps in social transition.[79] Based on the individual youth's needs, some forms of gender-affirming medical care may be medically necessary. Gender-affirming medical care that is provided in consultation with licensed healthcare providers is supported by extensive research and, based on the individual adolescent's needs, may be medically necessary.[80,81] Withholding timely gender-affirming medical care when indicated, withholding support for a gender-affirming exploratory process, and/or withholding support of social transition when desired, can be harmful because these actions may exacerbate and prolong gender dysphoria.[82,83]

Licensed healthcare providers play an important role in educating adolescents and their parents and caregivers about the various options for medical gender transition. They can also support youth, families, and caregivers in understanding this information and assess their understanding so that parents/caregivers and youth can provide fully informed consent and assent for the proposed care. The support of a behavioral health provider during these processes can aid an adolescent in identifying care needs, adjusting to their changing physical characteristics, and navigating responses from people in different aspects of their life.

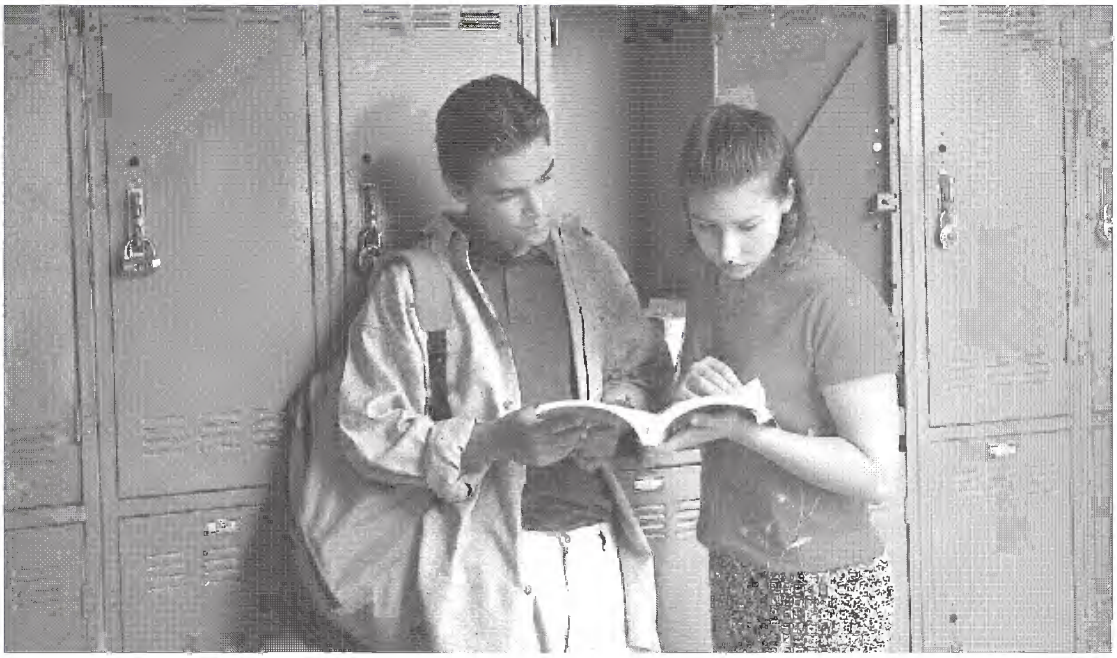
Policy Approaches to Support the Behavioral Health of LGBTQI+ Youth

LGBTQI+ youth and their families can benefit from policies that aim to:

- End harmful and ineffective efforts such as SOGI change efforts and ensure access to evidence-based care
- Promote behavioral health through protective and antidiscrimination policies
- Improve behavioral health through facilitating increased support from families, schools, and communities
- Conduct research that increases knowledge of health inequities with the goal to improve care

Given that SOGI change efforts are not appropriate therapeutic interventions, and are in fact harmful, immediate efforts are required to end their practice. Policy efforts to end SOGI change efforts have included:

- Passing state legislation to ban SOGI change efforts or provide supportive resources
- Introducing federal legislation to ban SOGI change efforts or provide supportive resources
- Banning licensed behavioral health providers from engaging in SOGI change efforts



- Restricting use of state funds and proposing the restriction of federal funds for these efforts
- Defining SOGI change efforts as consumer fraud

Efforts to improve understanding among behavioral health providers and other stakeholders of the harms of SOGI change efforts and the benefits of evidence-based care are essential. Other policy efforts can expand access to LGBTQI+ evidence-based care through reforming insurance and health services, ensuring nondiscrimination in health services programs, and increasing behavioral health and medical professional training in appropriate treatments. Bans on gender-supportive and gender-affirming care are harmful to individuals of diverse sexual orientation and/or gender identity.[84]

Policies can improve behavioral health and reduce health risks in this population by ensuring protection from discrimination, exclusion, and violence in schools and communities, and by expanding civil rights for LGBTQI+ individuals and families. Reducing stigma directed at LGBTQI+ individuals and families through affirmative public information that is respectful of families and youth from diverse religious, cultural, socioeconomic, and racial/ethnic backgrounds is important and consistent with professional ethical guidelines and standards of care. Supporting research to continue the development of evidence-based behavioral interventions for LGBTQI+ youth—especially those from diverse backgrounds—will contribute to the overall health and well-being of this community.

Introduction

This report, *Moving Beyond Change Efforts: Evidence and Action to Support and Affirm LGBTQI+ Youth*, revises and builds on the seminal 2015 SAMHSA publication, *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth*.[6] Based on the usefulness of the 2015 report, SAMHSA determined that a revision was warranted to reflect advances in scientific research and practice. This report provides an overview of current scientific understanding on sexual orientation and gender identity development and research on the behavioral health of youth of diverse sexual orientation and/or gender identity. The report also includes professional consensus on best practices in behavioral health with lesbian, gay, bisexual, transgender, queer, questioning, and other sexual- and gender-diverse youth (LGBTQI+ youth) and describes actions and policy options based on scientific research to improve their health and well-being.

"Section 1. State of the Evidence on SOGI Change Efforts With Youth" addresses sexual orientation and gender identity (SOGI; pronounced "SO-gee") change efforts. SOGI change efforts include practices that are not supported by credible evidence, are harmful, and have been disavowed by behavioral health experts and professional and scientific associations. "Statements of Professional Consensus on Beneficial and Harmful Practices With Youth of Diverse Sexual Orientation and/or Gender Identity" describes updated statements from experts on best practices in behavioral health for sexual and gender minority youth. "Sexual Orientation and Gender Identity Change Efforts With Youth" is an update on current research regarding SOGI change efforts in youth, and formed the basis for the best practice statements.

"Section 2. Development, Behavioral Health, and Beneficial Therapeutic Approaches With Youth of Diverse Sexual Orientation and/or Gender Identity: A Research Overview" provides an updated and expanded overview of recent research with LGBTQI+ youth beyond change efforts. This section summarizes new developments in research with youth of diverse sexual orientation and/or gender identity, including sexual orientation and gender identity development and behavioral health. It also discusses positive and negative influences on the behavioral health and well-being of LGBTQI+ youth, including factors such as family, school, community, and policy. Importantly, this section also provides information about appropriate and beneficial therapeutic approaches to support the behavioral health and well-being of youth of diverse sexual orientation and/or gender identity and their families.

"Section 3. Policy Approaches to Support and Affirm the Behavioral Health and Well-Being of LGBTQI+ Youth" provides a comprehensive

outline of scientifically supported recommendations for policies to improve the behavioral health and well-being of youth of diverse sexual orientation and/or gender identity, including improving access to comprehensive, supportive care.

SAMHSA aims to reduce the impact of substance use and mental illness on America's communities. As such, SAMHSA endeavors to improve public health and eliminate health inequities, including those affecting LGBTQI+ communities. By addressing the issues included in this report that have a significant impact on the lives and well-being of LGBTQI+ youth, SAMHSA aims to enable families, caregivers, providers, educators, and policymakers to take actions that will reduce the behavioral health risks and inequities facing this vulnerable population.

Revision Process

Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth, a 2015 SAMHSA publication, was reportedly helpful to behavioral health providers, families, school professionals, policymakers, and other audiences.[6] SAMHSA determined that the report's utility could be enhanced and updated to reflect new advances in scientific research and practice. The revision—this report—includes:

- New research on SOGI change efforts
- Latest developments and research in the field of gender identity and sexual orientation development in youth
- Updated guidance for behavioral health providers, families, caregivers, and school-based professionals
- New section on public policy considerations

The 2015 report was based on a meeting of experts led by the American Psychological Association. Building on the successful 2015 process, a revision framework was developed by the contractor that culminated in a 2-day online meeting on September 9-10, 2021. During the meeting, experts in relevant fields considered a comprehensive array of research findings, professional guidelines, the current clinical knowledge base, behavioral health concerns of youth of diverse sexual orientation and/or gender identity, and policy opportunities. During this meeting, the Subject Matter Expert Consensus Panel (the Panel) and scientific writing team, under the direction of the contractor, helped develop and formulate this report.

The experts were identified based on their knowledge of a wide array of topics, including but not limited to:

- Gender identity and sexual orientation development in youth, including nonbinary and transgender individuals
- Youth clinical issues, including those related to gender dysphoria
- Concerns of ethnically, racially, and culturally diverse communities and under-resourced and underserved populations
- Family psychology
- Community and school mental health
- Professional ethics
- Research methods
- Intersection of behavioral health and spiritual diversity
- Legal issues and public policy
- SOGI change efforts

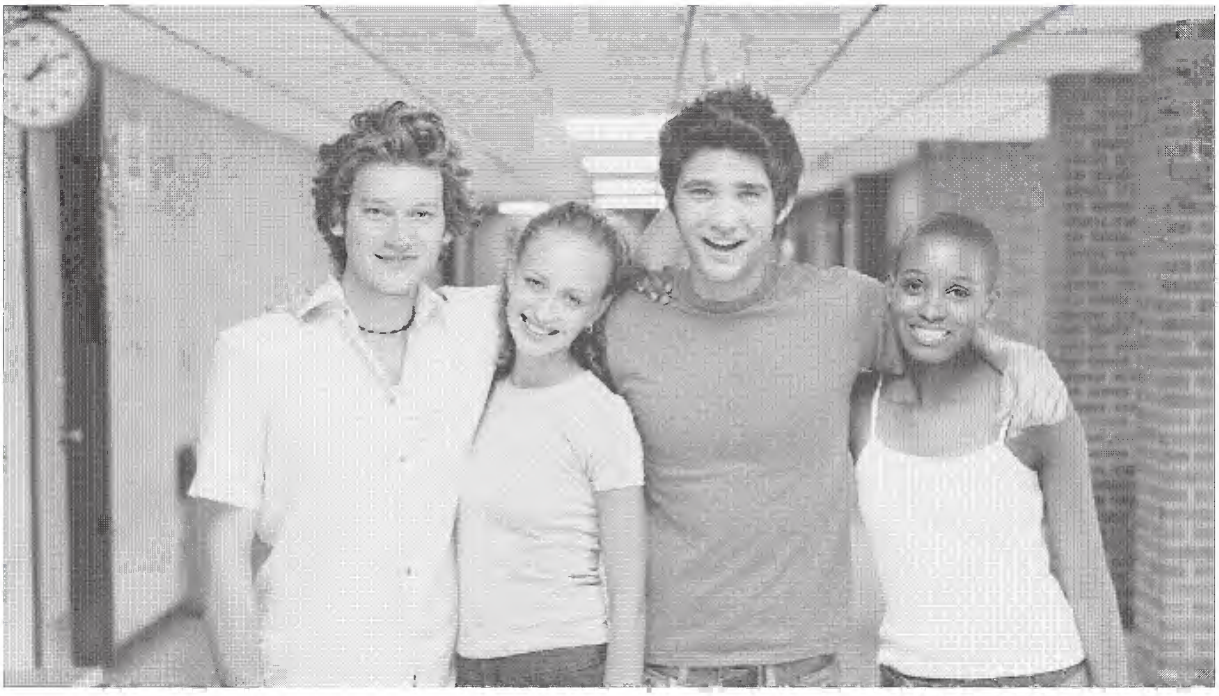
An extensive list of experts was generated from those with expertise in the above areas based on published research and innovation in the key knowledge areas; knowledge of, or participation in, the development of professional guidelines; expertise in clinical practice; referral by other

experts; and behavioral health specialty. SAMHSA also sought input from the experts who contributed to the 2015 report, including the American Psychological Association, and those who could assist in achieving the goals of this report.

Additional input was obtained from professionals in pediatrics, psychology, psychiatry, public health, social work, scientific research methodology, and legal issues and public policy. These individuals included researchers and practitioners in child and adolescent development and mental health, as well as researchers in gender development, gender identity, and sexual orientation in youth. The Panel, which helped develop and formulate this report, included experts with backgrounds in family therapy, ethnic, racial, and cultural diversity, needs of underrepresented populations, faith and psychology, and ethics. The Panel included those who practice in a variety of settings from different behavioral health specialties. (See Appendix D for members.)

As with the process developed for the 2015 consensus panel for the formulation of consensus statements, unanimous consensus was sought, but if it could not be reached, 80 percent support would constitute consensus. Versions of consensus statements were circulated after the September 2021 meeting with multiple opportunities provided for panelists to submit comments and revisions. Final versions were adopted by polling. Unanimous consensus was reached in nearly all instances. The statements of professional consensus are provided in "Section 1. State of the Evidence on SOGI Change Efforts With Youth."

Observers from SAMHSA's senior leadership team, internal experts, and cross-federal experts who had been involved in developing the 2015 report were present for the September 2021 meeting and offered the opportunity to submit written questions and input to the Panel throughout the meeting.



Section 1. State of the Evidence on SOGI Change Efforts With Youth

Statements of Professional Consensus on Beneficial and Harmful Practices With Youth of Diverse Sexual Orientation and/or Gender Identity

Guiding principles and statements of professional consensus regarding sexual orientation and gender identity and expression among youth were developed during the meeting of the Subject Matter Expert Consensus Panel (the Panel) meeting in September 2021 (see Revision Process in the previous section for a description of the Panel meeting and revision process). These statements revise and build on the professional consensus statements developed during a July 2015 American Psychological Association convening, as described in the 2015 report, *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth*.[6] The 2021 convening and resulting statements reflect updates to current evidence and recommended clinical practice.

Guiding Principles for Behavioral Health Providers

The Panel updated a statement regarding the guiding human rights and scientific principles that provide a foundation for behavioral health providers working with this population. They are based on codes of professional ethics for the fields of psychology, psychiatry, counseling, social work, and pediatrics.[70,74,83,84,85,86,87]

- Behavioral health providers respect human dignity and human rights. Professional ethics necessitate that children and adolescents be supported in their right to explore and actualize their own identities.

Though the terms "conversion therapy" and "reparative therapy" are commonly used, these efforts are not therapeutic and reinforce harmful beliefs that sexual- and gender-diverse people need repair or conversion.

- All children and adolescents should have fair and equitable access to behavioral health services that will benefit their health and welfare without the risk of harm. Children and adolescents have the right to participate in decisions that affect their health care and future lives.
- Behavioral health providers assist children, adolescents, and their families in making informed healthcare decisions by providing developmentally appropriate information and assessing their decision-making capacities and family and community contexts.
- Behavioral health providers strive to provide care that is in the best interest of the child or adolescent.
- Behavioral health providers strive to incorporate cultural awareness, respect, and sensitivity into their work. They recognize that age, gender identity and expression, race, ethnicity, culture, language, national origin, religion, spirituality, sexual orientation, different abilities, and socioeconomic status are important factors to consider when working with children, adolescents, and families.

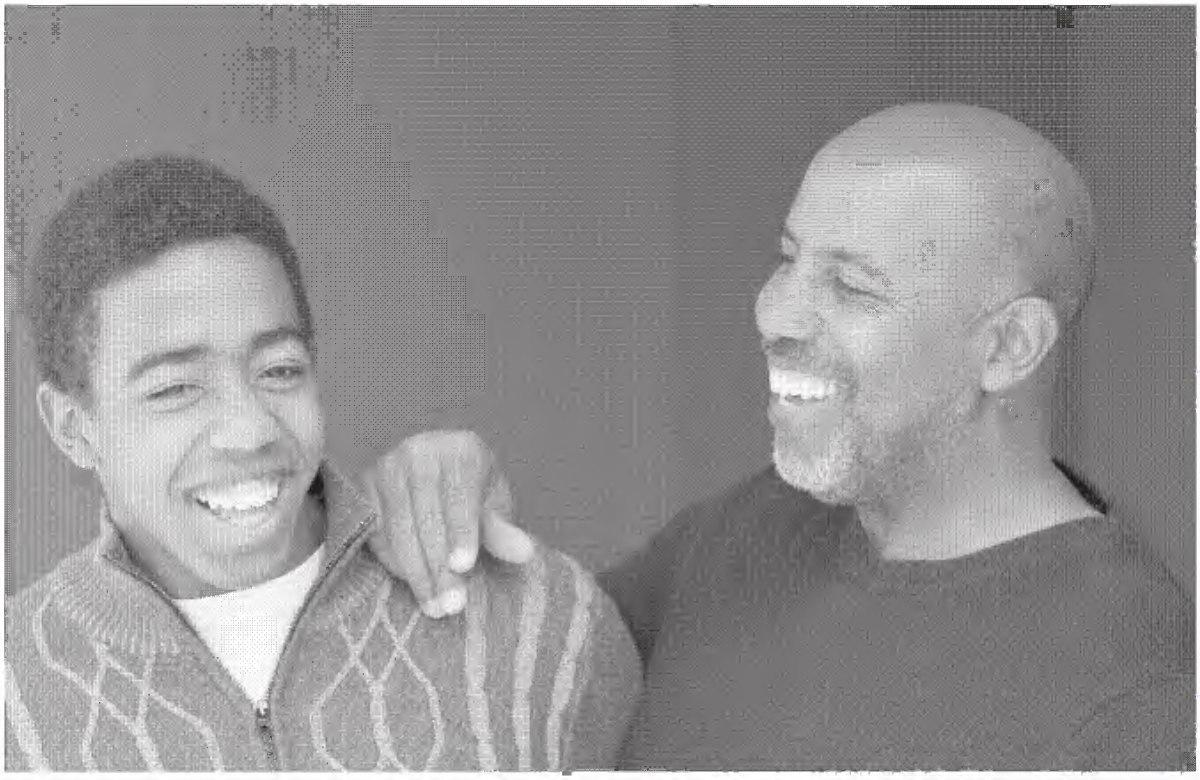
- Behavioral health providers strive to eliminate any impact of bias on their professional interactions and decisions.

Defining Sexual Orientation and Gender Identity Change Efforts

SOGI change efforts, commonly referred to as "conversion therapy" or "reparative therapy," are practices that aim to suppress or alter an individual's sexual orientation or gender to align with heterosexual orientation, cisgender identity, and/or stereotypical gender expression. SOGI change efforts are premised on or motivated by the belief that diversity in sexual orientation and/or gender identity and expression is a deficit, mental illness, or pathology.

SOGI change efforts do not include gender-affirming care. They do not include counseling that facilitates acceptance, social support, or open and affirming exploration and development of one's sexual or gender identity, including navigating sexual orientation and/or gender identity within the context of intersecting identities.

In the field of health care, the term "inappropriate" is used to designate care that is nonbeneficial, not medically indicated, and ineffective in achieving a patient's desired results. Medically inappropriate care is not needed or supported by clinical evidence and can result in negative health outcomes. The term "appropriate" is used to designate care when the expected health benefit exceeds the expected negative consequences by a sufficiently wide margin that the care is worthwhile.[88]



Professional Consensus on Sexual Orientation and Gender Identity Change Efforts With Youth

1. Variations in sexual orientation (including identity, behavior, and/or attraction) and gender (including identity and expression) are part of the normal spectrum of human development and do not constitute mental disorders.
2. Available research indicates that SOGI change efforts can cause significant harm. It also indicates that these efforts are not effective in altering sexual orientation. Further, no available research indicates that SOGI change efforts are effective in altering gender identity. No available research supports the claim that these efforts are beneficial to children, adolescents, or families.
3. SOGI change efforts are inappropriate practices that should not be provided to children and adolescents.
4. Rejection and lack of social and emotional support from families and communities negatively impact the health of sexual and gender minority youth. Such behaviors can cause harm, particularly family rejection of sexual orientation and/or gender diversity.

Professional Consensus on Appropriate Interventions With Youth of Diverse Sexual Orientation and/or Gender Identity and Their Families

1. Appropriate approaches to care for sexual and gender minority youth and their families:
    - Are evidence-based and person-centered
    - Reduce the rejection of sexual and gender minority youth
    - Increase family, school, and community support

    - Are responsive to children's, adolescents', and families' intersectional identities, including age, gender, race, ethnicity, culture, national origin, religion, spirituality, sexual orientation, different abilities, language, and socioeconomic status
2. Appropriate therapeutic approaches for sexual and gender minority youth do the following:
    - Provide accurate information on sexual orientation and gender identity and expression
    - Identify sources of distress for children, adolescents, and families and work with them to reduce it
    - Facilitate exploration and development of one's sexual and/or gender identity
    - Support adaptive coping to improve psychological well-being
    - Help youth navigate their sexual orientation, gender identity, and gender expression within the context of their cultural, religious, and other intersecting identities
3. Gender affirmation, including social transition (e.g., changing one's name, pronoun, and/or appearance), is appropriate and beneficial for gender minority children and adolescents.

Behavioral health providers may want to consult guidelines from major medical and mental health associations such as: American Academy of Child and Adolescent Psychiatry, American Academy of Pediatrics, American College of Physicians, American Counseling Association, American Medical Association, American Psychiatric Association, American Psychoanalytic Association, American Psychological Association, American School Counselor Association, Endocrine Society, National Association of School Psychologists, National Association of Social Workers, Pediatric Endocrine Society, Society for Adolescent Health and Medicine, World Medical Association, and World Professional Association for Transgender Health. (See Appendix C for some of these resources.)

Based on the youth's needs, gender-affirming medical care may be medically necessary. Such care is defined here as a care plan or service that is necessary to assess, maintain, or improve health and well-being and to avoid illness or reduce symptoms based on existing professional guidelines and scientific evidence. Withholding timely gender-affirming care when indicated, withholding support for a gender-affirming exploratory process, or withholding support of social transition when desired can be harmful because those actions may exacerbate and prolong gender dysphoria.

4. Legal prohibitions on gender-affirming care (including medical treatment) are harmful to children and adolescents. Further, policies that stigmatize, restrict, or exclude gender minority youth are harmful to children and adolescents.
5. When working with sexual and gender minority youth, behavioral health providers' ethical and professional responsibilities include delivering care that reflects respect, compassion, and cultural humility. It should be consistent with current professional, evidence-based, multidisciplinary resolutions and guidelines issued by leading health and scientific associations and professional ethical principles.

Person-centered, also known as client-centered, is a long-standing therapeutic approach that affirms and values all aspects of individuals.[89] It emphasizes unconditional positive regard and empathic understanding of all aspects of the person.

Professional Consensus on Education and Training

1. Like all youth, sexual and gender minority youth and their families have diverse cultural, ethnic, racial, religious, and other identities that shape their experiences, values, and behavioral health needs. These are important factors for behavioral health providers to understand and acknowledge. Providers should receive specific training in the development of diverse sexual orientations and gender identities, as well as training on culturally responsive approaches to working with sexual and gender minority youth and their families from diverse backgrounds.
2. While sexual and gender minority youth experience many of the same developmental milestones as other youth, they also encounter unique challenges and may need specific support and resources to thrive. All of those engaged in the care of youth, including parents and caregivers,

healthcare providers and staff, school and education professionals, community leaders, social service providers, legal professionals, and policymakers, can benefit from accurate, scientific, non-pathologizing information about sexual and gender diversity.

Sexual Orientation and Gender Identity Change Efforts With Youth

Over the past decade, additional high-quality research focused on documenting the practice and effects of SOGI change efforts has provided further evidence that these efforts should not be practiced with youth. This section includes a review of recent research on SOGI change efforts and information about their continued use across the United States. It also includes a detailed description of some of the methodological issues relevant to SOGI change efforts research that may be useful for researchers and policymakers. Finally, this section describes guidance from professional organizations disavowing SOGI change efforts.

Research on SOGI Change Efforts

There is now a significant body of research on SOGI change efforts. Overall, it has focused on sexual orientation change efforts more than gender identity change efforts. Although some study populations included both sexual and gender minorities, they often examined SOGI change efforts in ways that obscure whether transgender participants experienced change efforts related to their sexual orientation, gender identity, or both. This is both a methodological shortcoming of some SOGI change efforts research and a reflection of the realities of its practice, where it is not always possible to distinguish between sexual orientation and gender identity change efforts. For example, SOGI change efforts often include attempts to change children's and adolescents' gender expression to be more consistent with the stereotypical norms expected for their assigned sex at birth, with a goal to prevent both a transgender identity and a future diverse sexual orientation.[24,50,90]

In 2009, the American Psychological Association Task Force on Appropriate Therapeutic Responses to Sexual Orientation Change Efforts conducted an authoritative review of peer-reviewed literature published on sexual orientation change efforts.[24] Since its publication, a systematic review of research on sexual orientation change efforts has been published,[7] as well as quantitative and qualitative empirical studies examining sexual orientation change efforts among populations residing in the United States or Canada.[8,9,10,11,91,92,93,94,95,96,97,98,99,100,101,102,103,104]

A 2018 systematic review of research on gender identity change efforts published between 1990 and 2017 identified four studies reporting on its use, which consisted of three case reports and one case series.[105] Since then, three studies investigated gender identity change efforts among populations residing in the United States or Canada.[9,106,107,108] One study examined their use in New Zealand,[109] and several studies examined sexual orientation change efforts with transgender and gender-diverse populations in the United States and Canada.[10,11,103]

Lesbian, gay, bisexual, and other sexual orientations are normal variations of human sexuality and are not mental disorders. Transgender, nonbinary, and other gender identities are normal variations of human gender and are not mental disorders. Therefore, practices seeking to change an individual's sexual orientation, gender identity, and/or gender expression are not indicated and are inappropriate.

Several recent studies of SOGI change efforts reflect major methodological improvements over past work, such as larger sample sizes (e.g., 1,518[8]; 27,715[107]; 25,791[9]), a probability sample,[8] and controlling for other factors that may also cause harm (e.g., other adverse childhood experiences [ACEs]).[8] The majority of these studies were conducted with adults. One study included adolescents and young adults (ages 13-24),[9] and one study was limited to emerging adults ages 21-25 and asked about experiences of SOGI change efforts during adolescence.[10]

Research indicates that sexual orientation change efforts are not effective in altering sexual orientation. Research indicates that these efforts can cause significant harm, including suicide attempts and other negative behavioral health outcomes. No available research supports the claim that sexual orientation change efforts are beneficial to children, adolescents, or families.

Syntheses of research on sexual orientation change efforts have concluded that there is no evidence to support their effectiveness in altering sexual orientation or sexual attractions. A systematic review of peer-reviewed research on sexual orientation change efforts published from 1960 to 2007 concluded that they were not effective and may cause harm.[24]

Recent studies of sexual orientation change efforts corroborate those findings and provide stronger evidence of certain harms. Recent large, methodologically rigorous studies consistently find that exposure to sexual orientation change efforts places individuals at increased risk of suicidality and suicide attempts, as well as other negative outcomes including depression.[8,9,10,11] No studies have found evidence of any benefit of sexual orientation change efforts to children, adolescents, or their families. Other scholars and international organizations have independently conducted reviews of the sexual orientation change efforts literature, reaching the same conclusions.[7,12,13] It is now scientific consensus that sexual orientation change efforts are not effective and can cause significant harm.

No research indicates that gender identity change efforts are effective in altering gender identity. Research indicates that these efforts can cause significant harm, including suicide attempts and other negative behavioral health outcomes. No available research supports the claim that gender identity change efforts are beneficial to children, adolescents, or families.

SOGI change efforts have been used in an attempt to force children's behaviors, dress, and mannerisms to become more consistent with those stereotypically expected of their assigned sex at birth—that is, more stereotypically masculine expression for those assigned male at birth and more stereotypically feminine expression for those assigned female at birth. Historically, SOGI change efforts were the primary clinical approaches used with gender-diverse children, including those experiencing gender dysphoria.[39,50,90]

No research has demonstrated that gender identity change efforts are effective in altering

Despite evidence of harm, diverse populations across the United States, including children and adolescents, continue to be exposed to SOGI change efforts from a variety of licensed and unlicensed practitioners.

gender identity; there is also no evidence of any benefits of such practices to children, adolescents, or their families. Recent large, methodologically sound studies have investigated harms associated with gender identity change efforts.[9,107,108] These studies indicate that exposure to gender identity change efforts—in childhood, adolescence, and/or adulthood—is associated with harm, including suicidality, suicide attempt, and other negative mental health outcomes such as severe psychological distress.

Research that asked transgender participants about prior exposure to sexual orientation change efforts also reported that these efforts were associated with negative mental health outcomes including suicidal ideation and attempts.[10,11] Although this report focuses primarily on studies in the United States, a recent study in New Zealand corroborates findings of lasting harm associated with gender identity change efforts.[109] The findings of harm associated with SOGI change efforts—practices that exemplify anti-LGBTQI+ stigma and rejection—are bolstered by the extensive literature connecting minority stress, family/community rejection, and a lack of acceptance to negative health outcomes among youth of diverse sexual orientation and/or gender identity.[102,110,111]

Despite scientific consensus regarding the harms of SOGI change efforts and no evidence to support claims of its effectiveness or benefits, these efforts continue to be practiced across the United States by diverse health professionals and unlicensed community members.[8,9,106] It is estimated that anywhere from 3.5 to 18 percent of adults of diverse sexual orientation and/or gender identity have been exposed to SOGI change efforts; the single national probability sample reported a prevalence of 7 percent.[8] Its frequency of use among transgender and nonbinary populations is higher than that observed in cisgender LGB populations,[96,103,106,107] including in studies with adolescents and young adults.[9,10]

Though earlier reviews reported that most of the individuals who experienced sexual orientation change efforts were white men of higher socioeconomic status,[24] recent studies that rely on large national samples suggest greater diversity, indicating that women, people of color, and people from lower income levels are also affected by SOGI change efforts in the United States.[8,9,96,107]

Studies with individuals from religious traditions in which sexual orientation diversity and gender diversity are seen as contrary to faith teachings have often reported a greater prevalence of SOGI change efforts than studies that include individuals regardless of religious affiliation.[24,92,100,112] Based on these findings, it is likely that exposure to SOGI change efforts is greater among individuals from some religious backgrounds than those from more secular backgrounds.[24,91,100,112] However, current

Relative to young people who had not experienced SOGI change efforts, those who reported undergoing these efforts were more than twice as likely to report having attempted suicide and having multiple suicide attempts.[9]

research does not provide for estimates of prevalence.[91]

Of note, research indicates that younger generations may be at similar risk of exposure to SOGI change efforts as generations of youth before them.[8,103] As of 2018, adolescents and young adults from all regions of the United States reported exposure to these efforts.[9] A study of young adults of diverse sexual orientation and/or gender identity from community settings in the San Francisco area found that more than half had experienced SOGI change efforts from parents and caregivers, while just more than one-fifth had also experienced these efforts from an external source such as a religious leader or a behavioral health provider.[10]

Younger generations continue to be exposed to SOGI change efforts. Studies published recently show that adolescents and young adults across all regions of the United States continue to be exposed.[8,9,105]

Additionally, current research finds that SOGI change efforts result in negative consequences regardless of who attempts to effectuate the change. These change efforts are harmful whether undertaken by parents and caregivers, behavioral health providers, or other community members.[10,107] These findings indicate that efforts to reduce the harm caused by these practices would be most effective with a broad focus to include all forms of SOGI change efforts, as well as to reduce the stigma against LGBTQI+ people that drives their continued practice.

Methodological Considerations When Studying SOGI Change Efforts

Prospective, experimental research studies such as randomized controlled trials (RCTs) are considered a rigorous methodology for evaluating efficacy because these methods minimize selection bias and permit accurate estimates of causal effects. However, RCTs are not always an appropriate or ethical research design.[113] This is particularly true when multiple research studies indicate that a treatment or intervention is known to carry the risk to cause harm.[114]

To date, there have been no experimental research studies of SOGI change efforts with children or adolescents, nor would they be ethical to conduct. This is because there is sufficient evidence of harm associated with SOGI change efforts to conclude that they should not be provided to children and adolescents, and because previous studies have found no benefits. Coupled with the fact that professional consensus has established that diversity in sexual orientation and gender identity are normal variations for which treatment is unwarranted, an RCT is even more inappropriate to conduct. These ethical concerns are amplified in research with youth. Government regulations concerning research with children set strict limits and conditions on studies that could inappropriate to conduct. These ethical concerns are amplified in research with youth. Government regulations concerning research with children set strict limits and

conditions on studies that could pose harm to children and adolescents.[115]

There are valid ways to assess harm from SOGI change efforts without conducting an RCT or other rigorous quasi-experimental design (e.g., a nonrandomized design). Harm associated with an event or treatment can be evaluated through retrospective ("looking back") studies that examine the impact of those events and treatments by comparing outcomes for those who experienced them against people like them who did not. Mechanisms such as case studies, patient registries, and self-report surveys are also valid means to detect and report harms of a treatment.[114]

Most of the research using high-quality methodologies published since 2014 on sexual orientation or gender identity change efforts has been retrospective and employed cross-sectional designs, with adults asked to report their past experiences with change efforts at one point in time. This study design is appropriate for gathering evidence of harm. However, there are limitations to these study designs. Although they can identify harms, they cannot determine with certainty whether those harms are solely attributable to the SOGI change efforts. For example, research that relies on retrospective self-reports must address limits or differences in the accuracy of recollection of past events or experiences.

Sampling design—that is, how a research study recruits participants—can also limit the generalizability of the findings (i.e., the degree to which the results of a study can be applied to a broader group of people or situations). Much, though not all, of the research on SOGI change efforts uses what is called a "convenience sampling design," meaning it is unknown how representative the research participants are of all who have undergone these efforts. There is also natural bias in such samples because these are naturally occurring groups that share a common or similar social environment.

Current research on SOGI change efforts uses methodologies appropriate for the study of harm. Consistent findings across studies provide solid evidence that SOGI change efforts are harmful to the health of sexual and gender minority people, including children and adolescents.

Nonetheless, the public can have increased confidence in the research findings when many studies using a variety of research designs, conducted by independent research teams, consistently conclude that a "treatment" is associated with harm. This is the case with research on SOGI change efforts. Indeed, a strength of the existing research on these change efforts is the consistent finding that SOGI change efforts are associated with harms. This has been found across studies conducted by independent research teams using different methods and sampling strategies.

Despite methodological concerns that exist within specific studies, when taken together, the evidence is strong that SOGI change efforts are harmful to the health of people of diverse sexual orientation and/or gender identity, including children and adolescents. In recent decades, scholars and ethicists have proposed criteria for identifying potentially harmful behavioral health treatments when limited data exist. Potentially harmful treatments are defined as those that:

- Cause psychological or physical harm to the client or others
- Result in harmful effects that are long-lasting
- Have had independent research teams find and replicate the harmful effects[116]

This is the case with SOGI change efforts. Ineffective treatments—those that may not directly cause further harm but do not improve the health or well-being of the individual receiving treatment—may also be considered harmful in so far that they deprive an individual of needed care.[117,118]

Three sets of criteria have been proposed to identify potentially harmful treatments for children:

1. Criteria drawn from ACEs, revised to include experiences with therapists
2. Criteria drawn from studies of maltreatment and neglect
3. Criteria based on the plausibility of an intervention and its (in)congruence with what is known about child development.[119]

SOGI change efforts with children and adolescents meet all three criteria for identifying potentially harmful treatments for children.

Given the lack of evidence of efficacy and the potential risk of serious harm, every major medical, psychiatric, psychological, and professional mental health organization has taken measures to end sexual orientation change efforts and gender identity change efforts.

Consensus of Professional Organizations

Associations that have taken measures to end sexual orientation change efforts and/or gender identity change efforts include, among others:

- **Medical associations,** such as the American Academy of Child and Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, American Medical Association, American Psychiatric Association, and the Society for Adolescent Health and Medicine
- **Psychological associations,** such as the American Psychoanalytic Association, American Psychological Association, and National Association of School Psychologists
- **Counselor associations,** such as the American School Counselor Association and American Counseling Association
- **Social worker associations,** such as the National Association of Social Workers
- **International health organizations,** such as the Pan American Health Organization (of the World Health Organization), World Professional Association for Transgender Health, and World Psychiatric Association

Conclusion

There is sufficient evidence to conclude that SOGI change efforts are inappropriate, harmful practices based on the knowledge that:

- These efforts are founded on a view of sexual and gender diversity that runs counter to scientific consensus.
- Research demonstrates that sexual orientation change efforts are ineffective, and no research demonstrates the effectiveness of gender identity change efforts.
- There is a growing body of evidence that exposure to SOGI change efforts can cause significant, lasting harm.

Other supportive behavioral health approaches are recommended for individual or family distress associated with sexual orientation and gender identity, as discussed in "Beneficial Therapeutic Approaches and Interventions in LGBTQI+ Youth and Their Families" in Section 2.

Section 2. Development, Behavioral Health, and Beneficial Therapeutic Approaches With Youth of Diverse Sexual Orientation and/or Gender Identity: A Research Overview

Sexual Orientation

Sexual orientation consists of sexual identity, sexual and romantic attraction, and sexual behavior. Great shifts in the understanding of sexual orientation have occurred over the past century.[120] Though a diverse sexual orientation was once considered abnormal or a medical problem, scientists now understand that sexuality occurs on a continuum and that variations in sexual orientation are part of the normal and healthy range of human sexuality.[16,17,23,24,121]

Although some people experience changes in sexual awareness, attractions, behaviors, and identities over time, this does not mean that sexual orientation can be willfully changed through their own or others' efforts, such as through sexual orientation and gender identity (SOGI; pronounced "SO-gee") change efforts.[23]

Today, many terms are used to describe sexual orientation. In addition to terms such as lesbian, gay, bisexual, and straight, many young people use a wider range of descriptive identity labels for their sexual orientation such as pansexual, asexual, queer, and questioning, among others.[122,123,124] Research with large, national samples of adolescents has found that approximately one-quarter of adolescents of diverse sexual orientation and/or gender identity use newer descriptive labels for their sexual orientation and/or gender identity.[124,125] Use of a wider range of descriptive sexual orientation labels appears to be more common among gender-diverse adolescents than among cisgender adolescents.[123]

The number of people in the United States who feel safe or comfortable to self-identify as a sexual minority is increasing, and most of this increase is occurring among women, people of color, and younger generations.[31] Nearly 5 percent of adults in the United States identify as lesbian, gay, or bisexual; this represents an increase of nearly 60 percent of individuals who were comfortable self-identifying as LGB than on surveys conducted 8 years earlier. Among U.S. high school students, nearly 15 percent identify as lesbian, gay, or bisexual or are unsure of their sexual orientation; this is nearly double the number of students who were comfortable self-identifying as non-heterosexual in surveys

Sexual orientation and gender are distinct yet related.

Everyone has a sexual orientation, including identity, attraction, and behavior, and a gender, including identity and expression. Individuals can belong to both a sexual minority population (i.e., lesbian, bisexual, gay, and other non-heterosexual orientations) and a gender minority population (i.e., transgender, nonbinary, and other diverse genders). Importantly, gender does not determine a person's sexual orientation. Gender-diverse populations include individuals with many different sexual orientations, including those who identify as straight/heterosexual and those who identify with a sexual minority identity.

Though they are distinct, gender and sexual orientation are related. Many adolescents and young adults who are gender diverse also identify with a sexual minority identity.

conducted 8 years prior.[59] The true size of sexual minority populations is likely higher than reported in these surveys. Stigmatizing societal attitudes and concerns about confidentiality may limit accurate reporting of sexual orientation identity and behavior.[126] Additionally, many surveys ask about only a limited number of sexual orientation options (e.g., lesbian, gay, bisexual, or heterosexual), which may miss individuals who use other terms (e.g., pansexual, asexual, or queer).[122,124] The increase in openly identifying as a sexual minority does not suggest that people are more likely to have the innate characteristics of being a sexual minority, but rather that individuals are increasingly able to publicly identify as LGBTQI+ because of increasing awareness and acceptance of diverse sexual orientations; the expansion of laws, policies, and practices that protect and support individuals regardless of sexual orientation; and an increased willingness and ability among LGBTQI+ people to self-identify due to decreased stigmatization and greater access to civil rights.[31]

How many people in the United States are sexual and gender minorities?

An estimated 11.4 to 12.2 million adults identify as LGBTQ+ in the United States, a number roughly equivalent to the population of Ohio.

An estimated 1.99 million adolescents ages 13 to 17 identify as LGBT in the United States, which is roughly equivalent to the combined populations of Dallas, Texas, and Detroit, Michigan.[31,127,128]

Sexual Orientation Development in Youth

Sexual orientation is usually conceptualized to begin at or near adolescence with the development of sexual feelings.[24] The average age at which sexual minority individuals reach important sexual orientation identity development milestones, such as becoming aware of same-sex attractions and coming out to others, commonly occurs during adolescence.[129,130] Various factors affect the trajectory of development related to sexual orientation, and there is no single or simple trajectory experienced by all individuals.[131,132,133,134,135] Recent generations of sexual minority individuals tend to reach milestones related to sexual orientation identity development and coming out (e.g., first becoming aware of their attractions, disclosing or sharing one's sexual orientation- or gender-diverse identity, first sexual minority relationship) at similar ages in adolescence.[129] In addition, it is becoming increasingly common for children to identify as lesbian, gay, or bisexual in childhood.[18] Youth's earlier public self-identification as having a minority sexual orientation is likely due to reduced stigma related to sexual orientation diversity. As more youth self-identify as sexual minorities, scholars have called for supporting the emotional and mental health needs that children express related to their sexual orientation.[136]

Sexual identity development is influenced by cultural factors that may differ across racial and ethnic groups. However, most research on sexual orientation identity development has included primarily white youth without examining differences related to race and ethnicity or cultural background.[124] As such, our cultural and scientific understandings of common experiences and developmental trajectories of sexual minority populations may better reflect the experiences of white sexual minority groups and be less relevant to the experiences of sexual minority people of color.[137] Limited research has examined the dual or multiple identity development processes among sexual minority youth of color.[138] Development related to racial/ethnic identity and sexual identity may occur concurrently among adolescents, though

involve different processes.[139,140,141] A variety of studies have identified cultural constructs and culturally specific expectations that have been identified as influencing sexual identity development among youth of color include familism (i.e., family needs take precedence over individual needs) and specific cultural understandings and expectations of masculinity among Black and Latino adolescent boys in particular.[138,142,143,144]

Significant physical, cognitive, and social development occurs during adolescence. Sexual minority adolescents face the same developmental tasks that accompany adolescence for all youth, including sexual identity development. However, sexual minority adolescents must also navigate an environment lacking awareness and acceptance of socially marginalized sexual identities, potentially without family, community, or societal support.[145,146]

Sexual identity development includes processes of identity formation (i.e., becoming aware of sexual attractions, exploring sexual feelings) and identity integration (i.e., integrating sexual identity within the larger view of self).[145] For sexual minority adolescents, difficulty with the identity development process, such as difficulty accepting one's sexual orientation and dissonance between one's self-image and cultural, religious, and societal beliefs about sexual minorities, can increase negative views of one's own and others' sexual minority identities and lead to adopting negative societal attitudes and beliefs about being a sexual minority.[147]

Sexual orientation conflict has been linked to negative psychosocial outcomes in adolescents and young adults.[146] Furthermore, a negative self-image as a sexual minority youth contributes to the relationship between sexuality-specific stressors (e.g., family

When discussing the concept of gender, scientists distinguish among a person's sex assigned at birth, gender identity, and gender expression.[24,25,125]

- **Sex assigned at birth is typically based on the appearance of external genital anatomy; male, female, or intersex are possible ways to identify sex.**
- **Gender identity refers to a person's deep internal sense of being female, male, a combination of both, somewhere in between, or neither.**
- **Gender expression refers to the external way a person communicates their gender, such as with clothing, hair, mannerisms, activities, or social roles. A person's gender expression may or may not be consistent with culturally prescribed gender roles or their sex assigned at birth and may or may not reflect their gender identity.**

rejection, victimization) and poorer mental health outcomes.[146,147]

Positive identity development, however, is associated with better mental health among sexual minority adolescents.[145,148] For example, one study found that for sexual minority college students, those who reported strong religious beliefs also reported lower psychological distress, but only among those students who had high levels of self-acceptance of their sexual orientation.[149] Strong religious beliefs on their own were not protective in terms of psychological distress for students who reported lower levels of self-acceptance of their sexual orientation.

Important areas of focus for behavioral health providers who work with adolescents include helping them address negative views about aspects of their identity and supporting positive identity development. For behavioral health providers who work with sexual minority adolescents, this includes reducing the client's negative views of their own sexual orientation identity and supporting positive identity development. This encompasses the integration of sexual orientation identity into the adolescent's larger sense of self, alongside intersecting identities (e.g., cultural, racial/ethnic, and other identities).

Gender

Transgender is a term that refers to individuals whose gender identities are incongruent with their sex assigned at birth.[75] The term gender diverse is a broader term that includes transgender individuals, as well as others whose gender behaviors, appearances, or identities are incongruent with those culturally expected based on sex assigned at birth.[75]

Significant advances have occurred over time in the scientific understanding of gender. It is now understood that gender diversity—identifying with a gender that does not align with sex assigned at birth, and/or having a gender expression that varies from that which is culturally expected for one's gender or sex assigned at birth—is part of the normal and healthy spectrum of human diversity, is not pathological, and does not require clinical attention on its own.[19,22,25,150]

Gender diversity was depathologized with changes made to the 5th revision of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and the 11th revision of the International Classification of Diseases (ICD-11).[151,152] These changes make it clear that gender diversity is not a disorder. Instead,

current guidelines focus on treating and supporting individuals who may experience feelings of distress (i.e., gender dysphoria) or incongruence between their gender identity and body or sex assigned at birth, as well as any distress associated with stigma and discrimination.[25] Note that throughout this report, "gender dysphoria" (not capitalized) refers to the general concept of distress associated with incongruence between one's gender identity and body or sex assigned at birth, while "Gender Dysphoria" (capitalized) refers to the DSM diagnosis.

Access to gender affirmation can alleviate or improve distress due to feelings of gender incongruence. Gender affirmation refers to processes by which an individual is recognized and affirmed in the gender with which they identify.

Gender affirmation can include psychological, social, medical, and legal aspects. Access to gender affirmation can reduce gender dysphoria and improve mental and physical health outcomes among transgender and gender-diverse people and is protective against the negative effects of gender-related stigma and discrimination.[153,154] There is substantial evidence of the behavioral health benefits of access to gender affirmation for transgender and gender-diverse children, adolescents, and adults.[51,52,53,80,81,155,156]

The belief that people can only belong to one gender category—male or female—has been prevalent in many contemporary Western societies. However, over the past several decades there has been a growing scientific understanding that sex and gender are more complex. Some people are born with sex characteristics that fall outside of male and female categories, and gender identity occurs on a spectrum.[157,158,159,160,161]

Scientists now recognize that many gender identities and gender expressions exist, and have always existed in a wide range of cultures across history.[157,162,163,164]

Terms such as nonbinary, gender queer, gender fluid, agender, bi-gender, and others are used by many individuals to express their gender identity.[162,164]

Identifying with more than one identity is also common.[165] There are also many culturally specific terms that have long been used for third gender or nonbinary identities and gender roles, including two-spirit among some Indigenous North American cultures, fa'afafine in Samoan culture, and māhū in Native Hawaiian culture.[165,166,167,168]

What about intersex youth?

Intersex is an umbrella term used to describe people born with differences in sex characteristics, such as reproductive anatomy, chromosomes, or hormones that do not fit typical definitions of male and female. Intersex people can have many different gender identities.

Individuals with intersex traits may identify as male, female, nonbinary, or a different gender. Intersex individuals may consider themselves transgender if they do not identify with their sex assigned at birth.

Like other LGBTQI+ youth, intersex youth experience pervasive stigma and discrimination. The Federal Government has taken steps to reduce disparities facing people who are intersex, such as issuing a Request for Information on Promising Practices for Advancing Health Equity for Intersex Individuals in February 2023.[46]

Identifying as nonbinary appears to be more common among younger generations.[165] This may be related to greater visibility and social acceptance of gender diversity.[122] One study with a large national sample found that nearly one-quarter of adolescents of diverse sexual orientation and/or gender identity self-identified as nonbinary.[124] Of note, some people who describe themselves as nonbinary or another gender consider themselves transgender, while others do not.[158]

In this report, "transgender and gender diverse" is used as a broad term that refers to people whose gender identity and/or gender expression are incongruent with their sex assigned at birth, including binary transgender people, nonbinary people, and cisgender people with a diverse gender expression.

Estimates of the size of the transgender and gender-diverse population in the United States vary. It is only in recent years that some national, population-based surveys have started to include questions to assess gender identity, and the practice remains far from widespread. It is estimated that between 0.1 and 2.0 percent of adults in the United States identify as transgender.[124,169] These figures likely underestimate the size of the transgender and gender-diverse populations, because much of this research has not used current best practices for asking separately about current gender identity and sex assigned at birth and did not consistently include gender-diverse individuals who do not identify with the term transgender.[170,171] Recent population-based research with adults of diverse sexual orientation and/or gender identity has found that 1.2 million adults in the United States identify as nonbinary, including people who both do and do not consider themselves transgender.[158]

Research with high school students has found that between 1.1 and 9.2 percent identify as transgender, nonbinary, or another gender identity that differed from their sex assigned at birth.[122,171,172,173] Studies that specifically asked about identifying as nonbinary and other gender identities in addition to identifying as transgender reported larger proportions of transgender and gender-diverse youth, emphasizing the importance of asking about nonbinary and other diverse gender identities.[169,171,174]

Gender Development in Youth

Gender-related development begins in early childhood and progresses through adolescence.[21] Processes of gender-related identity development among transgender and other gender-diverse populations are varied, non-linear, and not necessarily anchored to specific ages or developmental periods.[37,38] For some individuals, gender identity appears stable across development, while others experience changes in their gender identity over time.

Youth who start to think of themselves as transgender or gender diverse may share this identity with others, and take steps in social transition across a wide range of ages.[29,30,177,178] There is no single developmental trajectory for transgender and gender-diverse youth—that is, there is healthy and normal variation in the age that youth recognize themselves as gender diverse.[25]

Individuals who exhibit gender diversity in childhood include those who:

- Consistently identify with a gender that differs from their sex assigned at birth
- Identify with the gender that aligns with their sex assigned at birth and have a diverse gender expression
- Are exploring their gender identity and/or gender expression[179,180]

While earlier research from clinics specializing in childhood gender identity suggested that many individuals who exhibited gender diversity in childhood did not later identify as transgender in adolescence, significant methodological weaknesses preclude use of these findings to identify trajectories of gender identity development and their associated frequencies.[180] However, more recent research and clinical expertise suggests that children who consistently identify with a gender different from their sex assigned at birth typically express a similar clarity in adolescence.[50,77,150,179,181,182] Research also indicates that children whose gender expression differs from social norms, but who do not identify as transgender or nonbinary, are more likely to have a diverse sexual orientation in adulthood.[24,183,184]

A significant body of research demonstrates that affirming a child's current gender identity and gender expression, as well as supporting their process of understanding more about their identity, is beneficial for all children. The benefits of providing affirming mental health care include reducing the risk of suicide in transgender and gender-diverse youth. Given the significant mental health risks that gender minority youth face when affirming mental health care is not available, affirming mental health care is appropriate and necessary even for youth who may later identify differently in adulthood.[78,179,185,186,187]

Younger generations understand, experience, and communicate their gender-related experiences in different ways than previous generations. These understandings of gender include an increased recognition of the complexity of gender, sexuality, and identity and fewer stereotypes or expectations of what it means to be a certain gender.[157,175,176]

Children who identify as transgender early in their development are increasingly supported and affirmed in their identities by many families at young ages. Research with transgender youth who have socially transitioned—that is, who present as their gender identity in everyday life—provides evidence that early in childhood, gender-related development is similar among transgender and cisgender children with the same gender identity, regardless of sex assigned at birth.[188,189,190] These similar areas of gender-related development between transgender and cisgender children include consistency and strength of identification with their gender and expression of gender preferences, stereotypes, behaviors, and beliefs.[40]

Other youth identify as transgender or gender diverse for the first time in adolescence.[35,177,191,192,193] Puberty can be a pivotal time when youth become more aware of their gender and experience physical changes that can trigger or exacerbate dysphoria.[194] Some individuals who initially identify as transgender or gender diverse in adolescence do not have a history of gender diversity or gender "non-conforming" behaviors or preferences in childhood.[178] This can make disclosure of a gender identity that differs from sex assigned at birth in adolescence surprising to parents, guardians, and others.

Some adolescents who identify as transgender or gender diverse report that they felt different at a young age but expressed or engaged in behaviors that were stereotypical for their sex assigned at birth earlier in life, while others do not feel differently about their gender until adolescence.[35,177] Given the advances in scientific understanding of the normal and healthy diversity of gender identities, understanding the current experiences of youth whose gender incongruence presents in adolescence is an important area of study. No singular narrative can describe the totality of transgender and gender-diverse youth experiences.

Identity development is among the key tasks of adolescence for all adolescents, including those who are transgender and gender diverse. Self-acceptance of one's gender identity, identity pride, and valuing self are factors that promote resilience among transgender and gender-diverse adolescents.[146,195,196,197] However, transgender and gender-diverse adolescents may experience identity conflict when reconciling a gender identity that may diverge from the expectations of their family, peers, and community. This can be particularly pertinent for transgender and gender-diverse adolescents of color, who often experience multiple forms of discrimination (e.g., racial discrimination when seeking out supportive services, or anti-transgender stigma in one's racial/ethnic or cultural community) and may perceive incompatibility between their gender identity and racial/ethnic identities.[141,199]

Conversely, racial/ethnic identity development processes may beneficially impact how youth navigate gender identity development, such as experience coping with adversity and developing a sense of pride in one's identity.[196] While self-acceptance and identity pride are associated with well-being, adopting negative societal attitudes and beliefs about being transgender or gender diverse and having a negative gender-related self-concept have been connected to mental health challenges and greater substance use among transgender and gender-diverse adolescents.[200,201]

Minority stressors experienced due to anti-LGBTQ+ stigma include major life events, such as assault because of one's sexual orientation, gender identity, or gender expression, as well as everyday forms of discrimination and non-affirmation, such as receiving poor services, being assumed to be straight, or being misgendered. Minority stress is also caused by policies that limit the opportunities, resources, and well-being of LGBTQI+ populations.[111,198]

Important areas of focus for behavioral health providers who work with adolescents includes helping them address negative views about aspects of their identity and supporting positive identity development. Therefore, important areas of focus for behavioral health providers who work with transgender and gender-diverse adolescents are reducing negative views of their own gender identity and supporting positive identity development.[199,200,201] As with adolescents of diverse sexual orientations, this includes integration of gender identity and gender self-concept into their larger sense of self, alongside cultural, racial/ethnic, and other identities.

Research on how gender identity development varies by gender, race and ethnicity, and other cultural, social, and environmental factors remains in its early stages. Some studies have identified potential differences in developmental trajectory by gender.[35] Many studies have disproportionately low representation of transgender girls and other gender-diverse youth assigned male at birth, suggesting that transgender girls and women are coming out at later ages.[202,203,204]

One study investigating age upon accessing gender-affirming medical care found that it was influenced by contextual factors, such as family religion, having a helpful caregiver, as well as developmental milestones reached upon recognition of gender incongruence and age at coming out or disclosing gender identity.[205] Another study of young transgender women found differences by racial/ethnic group, suggesting that youth of color may achieve some social milestones (e.g., disclosure of gender identity) at younger ages than white youth.[206]

Most research with transgender and gender-diverse youth has been conducted with mostly white, higher income families living in urban areas who have access to specialized pediatric gender clinics. In recent years, more research has been conducted with nonclinical populations of children.[36] Given the tremendous variation in attitudes and expectations related to gender by cultural group and family background, more research is needed with racially and ethnically diverse children and families, lower income families, and families from different cultural and religious backgrounds to better understand the experiences and needs of diverse gender minority children and adolescents and to ensure access to evidence-based care.

Health and Well-Being of LGBTQI+ Youth

In the United States and worldwide, sexual- and gender-diverse populations experience inequities in many behavioral health outcomes.[207,208] This report uses the phrase "health inequities" as opposed to "health disparities" to refer to unnecessary and avoidable health differences.[209] These health inequities are not caused by one's sexual orientation, gender identity, or gender expression, but rather by anti-LGBTQI+ stigma that is embedded in proposed and enacted laws, policies, and societal attitudes.

The Minority Stress Model provides an empirically validated conceptual model for understanding how stress due to anti-LGBTQI+ stigma, coupled with general life stressors, puts individuals of diverse sexual orientation and/or gender identity at increased risk for negative behavioral health outcomes.[111,210,211] These external experiences of minority stress cause cognitive, affective, and behavioral reactions, such as internalized stigma, identity concealment, and social isolation, all of which are associated with poorer mental health.[154,210,212,213,214]

Despite the impact of anti-LGBTQI+ stigma, which individuals can experience in tandem with other forms of discrimination, many youth and adults of diverse sexual orientation and/or gender identity can adapt, thrive, and demonstrate resilience despite risk exposure, high levels of stress, and other forms of adversity.[215] Resilience refers to a dynamic process of adapting positively within the context of significant adversity.[216] Resilience among sexual- and gender-diverse populations is promoted through:

- Self-acceptance of sexual orientation and gender identity, self-esteem, and identity pride
- Social support and sexuality- and gender-specific support from family, peers, schools, and community organizations
- School and community connectedness
- Inclusive and supportive federal and state policies[60,66,148,217]

It is important to recognize that sexual and gender minorities are not a single, homogeneous population. In addition to including individuals with many distinct sexual orientations, gender identities, and gender expressions, LGBTQI+ populations are also diverse with respect to other identities, including age, race, ethnicity, immigration status, language, national origin, religion, spirituality, ability, and socioeconomic status. Individuals with multiple minority identities experience unique stigma and stressors, as well as unique opportunities for resilience.[197,218,219,220]

To support individual LGBTQI+ youth in achieving their optimal health and well-being, and to take action to address health inequities among LGBTQI+ populations, behavioral and other healthcare providers, families, school administrators, boards, and educators, community leaders, and policymakers must understand the health concerns that may affect LGBTQI+ youth and be knowledgeable about the factors that lead to risk and resilience among LGBTQI+ youth. The following sections provide an overview of behavioral health concerns among LGBTQI+ youth, as well as what is known about the influence of families, school, religion and spirituality, community climate and policies, and gender affirmation on the behavioral health of LGBTQI+ youth.

Behavioral Health Concerns Among LGBTQI+ Youth

Variations in sexual orientation (identity, behavior, and/or attraction) and gender (identity and expression) are part of the normal spectrum of human development and do not constitute mental disorders. However, youth of diverse sexual orientation and/or gender identity are at elevated risk for mental illness and substance use due to experiences of discrimination related to sexual orientation, gender identity, rejection, trauma, violence, and a lack of support from families, school systems, and communities.[111] Transgender and gender-diverse children and adolescents may also experience psychological distress related to gender dysphoria.[25] It is important to emphasize that youth of diverse sexual orientation and/or gender identity are

resilient, and that with sufficient support and access to resources, they can thrive.[68,69] Behavioral health concerns that behavioral health providers can be aware of and attend to among sexual- and gender-diverse youth are summarized below.

Behavioral Health Concerns Among LGBTQI+ Children

Recent research has begun to investigate behavioral health among sexual- and gender-diverse children and has found that inequities in behavioral health may begin in childhood. While some sexual- and gender-diverse children are distressed, others are not. Among those who are distressed, the source of distress varies.

Several studies found that more children who self-identify as gay, bisexual, or questioning reported distress, including mood disorders, non-suicidal self-injury, suicide ideation, and suicide attempts than did children who do not identify as gay, bisexual, or questioning.[30,54] Additionally, two longitudinal studies found that children who later identified as a sexual minority began experiencing mental health challenges as early as age 11.[55,56] Other studies indicate that mental health concerns among sexual minority children may be linked to experiences of victimization, such as bullying behaviors perpetrated by peers.[221,222]

Gender-diverse children appear to have elevated rates of mental health concerns, including symptoms of anxiety and depression, history of self-harm, and suicidality, compared to cisgender children.[223,224,225] When gender-diverse children have behavioral health concerns, these may be related to invalidation or rejection of their gender diversity, or distress related to current anatomical dysphoria and/or anticipation of future pubertal development incongruent with their current gender. Alternatively, their mental health concerns may be entirely unrelated to their gender.[25,50]

At the same time, research also suggests that gender-diverse children who receive meaningful gender identity support do not necessarily experience elevated rates of depression and anxiety.[51,226] Research with a national sample of socially transitioned prepubescent transgender children found this group to have developmentally normative levels of depression, only minimal elevations in anxiety, and comparable levels of self-worth, suggesting that behavioral health concerns are not inevitable among this group.[51,226]

Behavioral Health Concerns Among LGBTQI+ Adolescents

As LGBTQI+ adolescents navigate the challenges of adolescence, some experience a variety of behavioral health concerns and psychosocial challenges. Compared to their heterosexual and cisgender counterparts, some adolescents of diverse sexual orientation and/or gender identity are at disproportionate risk of behavioral health symptoms, driven by increased exposure to stigma, rejection, and victimization.[48,227,228,229,230] It is also important to note that behavioral health concerns may be unrelated to sexual and gender diversity. Exposure to SOGI change efforts is a key risk factor that has been shown to increase risk of

suicide attempt among adolescents and young adults of diverse sexual orientation and/or gender identity.[9,10,49,229]

Compared to heterosexual and cisgender peers, adolescents of diverse sexual orientation and/or gender identity are more likely to experience psychological distress, symptoms of depression, and symptoms of anxiety.[57,65] Studies indicate large differences in rates of suicidal ideation and attempts among adolescents in the United States by sexual orientation and gender identity. The Youth Risk Behavior Surveillance System (YRBSS) documented increased odds of suicide risk among both sexual minority and gender minority high school students compared to heterosexual and cisgender students, including suicide attempt requiring medical treatment.[227,228,230,231]A recent public health study with data from six states found that while suicide rates are dropping, sexual minority adolescents in this study were three times as likely to attempt suicide relative to heterosexual adolescents.[58] Research with gender minority adolescents has documented that between 25 percent and 51 percent of transgender and gender-diverse adolescents have attempted suicide, with the highest rates among transgender boys and nonbinary youth.[192,232,233,234]

Research using YRBSS data indicates that some adolescents of diverse sexual orientation and/or gender identity are more likely than heterosexual and cisgender adolescents to engage in substance use.[228,229,231,235,236] Research found that adolescents of diverse sexual orientation and/or gender identity also experience greater incidence of eating disorders and disordered eating behaviors than their heterosexual and cisgender counterparts.[237]

Adverse mental health outcomes tend to be more prevalent among gender minority youth compared to sexual minority youth due to specific stigma and discrimination against transgender individuals.[61] The higher rates of substance use and suicidality are partly explained by experiences of discrimination, victimization, and higher rates of depressive symptoms reported by transgender and gender-diverse adolescents as compared to cisgender adolescents.[60,233,238,239,240]

Among transgender and gender-diverse adolescents, some research suggests that mental health outcomes may be worse among nonbinary adolescents and transgender boys.[61,232,241,242] Gender dysphoria, which can initiate or intensify in adolescence, can cause psychological distress among transgender and gender-diverse adolescents.[25] Increased experiences of victimization, rejection, and exposure to discriminatory policies may also drive the higher rates of adverse mental health seen among transgender and gender-diverse adolescents compared to sexual minority adolescents.[228,242,243]

Trauma is also a common behavioral health concern among adolescents of diverse sexual orientation and/or gender identity, who have an increased likelihood of experiencing child maltreatment, school-based victimization, violence, and homelessness, and who are overrepresented in both the child welfare system and the juvenile correctional system.[63,64,227,228,231,243,244,245,246,247]

A number of studies suggest that some neurodiverse youth are gender diverse.[224,248,249,250,251] The most recent clinical guidelines suggest that such youth benefit from an individualized approach to treatment.

The fact that research consistently demonstrates large inequities in behavioral health among LGBTQI+ adolescents indicates that this is a vulnerable population that needs psychosocial support, equitable social conditions, and access to affirming mental health care. At the same

time, it is important to emphasize that many LGBTQI+ adolescents are resilient and although experiencing discrimination and behavioral health challenges can thrive.[68,69,252,253]

Influences on Health and Well-Being

The increased risks of behavioral health distress that LGBTQI+ youth face are not a function of their identities. Rather, these risks stem from the stresses of stigma, discrimination, rejection, and violence.[240] The presence of sexual orientation- and gender-related stressors—and opportunities for emotional support and connection—encompasses multiple social systems, including, for instance, family, culture, values, school, and community networks.[254,255,256] Therefore, when LGBTQI+ youth are evaluated by a behavioral health provider, assessment should routinely include family, school, and community systems in which they live to identify both sources of distress and sources of support and connection as protective factors.[256] By increasing LGBTQI+ youth's access to support and resilience-promoting resources across their daily environments, and decreasing exposure to stigma and discrimination in communities and healthcare systems, more LGBTQI+ youth can achieve optimal health and well-being.

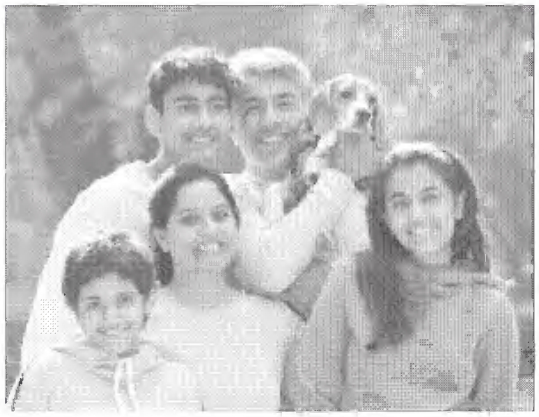
Family

Family response to youth's sexual orientation, gender identity, or gender expression has a significant impact on the youth's well-being, with effects that appear to extend into young adulthood.

Parents, caregivers, and families can serve as both a source of stress and a source of support for youth of diverse sexual orientation and/or gender identity.[40,53,257] Negative parental responses to sexual orientation, gender identity, and/or gender expression are associated with mental health concerns including psychological distress, depression, suicidality, and substance use.[10,253] Alternatively, parent-child relationships characterized by closeness and support are an important correlate of mental well-being.

Strong parental support for a child's gender identity may offset the mental health challenges commonly documented among gender-diverse children.[51,226] The use of a transgender or gender-diverse adolescent's chosen—rather than given—name has been linked to decreased depressive symptoms, suicidal ideation, and suicidal behavior.[49,52] Among adolescents of diverse sexual orientation and/or gender identity, high levels of sexual orientation and gender identity acceptance from parents and other relatives has been associated with reduced suicidality.[49,258,259] Further, the behavioral health benefits from high levels of family acceptance of youth's diverse sexual orientation and/or gender identity appear to last through young adulthood.[103] The limited research that has focused on family members outside of parents and primary caregivers suggests that siblings and extended family members can be key sources of support for youth of diverse sexual orientation and/or gender identity.[260,261]

Studies have found that some adolescents of diverse sexual orientation and/or gender identity report strikingly high rates of adverse childhood experiences (ACEs). High ACE scores and parental rejection have been associated with



suicidality in youth of diverse sexual orientation and/or gender identity[262] and may put these adolescents at greater risk for being victimized in other settings.[263] Notably, though some scholars and practitioners consider SOGI change efforts from family members potentially traumatic events, ACE measures do not capture youth's experiences of SOGI change efforts.[120]

It is important to note that some LGBTQI+ youth who lack family and/or parental support find resilient ways to access needed support and guidance. Many people of diverse sexual orientation and/or gender identity, including those with and without supportive families of origin, form "chosen families" with sexual- and gender-diverse friends who provide social support and resources.[266] In urban areas across the United States, LGBTQI+ adolescents and young adults of color—particularly Black and Latino youth—may join informal communities and LGBTQI+ family structures.

Religion & Spirituality

When considering family and community influences, a child's or adolescent's religious background is an important factor. Religious beliefs and background are far-reaching influences that encompass multiple arenas of one's life, including personal and family religious identity, beliefs, and coping; family attitudes, beliefs, and relationships; and community character and support. Religious views of sexual and gender diversity in the United States vary widely[269,270] and can have a large influence on sexual- and gender-diverse adolescents' mental health and well-being.[147,269,270] When working with youth of diverse sexual orientation and/or gender identity, it is important to consider the intersection of religion with youth's racial and ethnic identity and cultural background.[271,272]

Religion and spirituality are complex, nuanced aspects of human diversity. Parents from all backgrounds have a full range of reactions to their child's sexual orientation and gender identity and expression regardless of religious or spiritual traditions (e.g., confusion, desire for information, questions about social implications, love and loyalty, coming to terms with differences, growth and expansion of spiritual understanding, and for some a sense of loss).[273,274] Rather than focus on faith beliefs, where they might lack expertise, behavioral health providers can focus on encouraging key measurable behaviors among families and caregivers that have been found to be supportive and protective for children, as well as informing families how some of their behaviors and interactions might lead to negative behavioral health outcomes.[102,258,273]

Youth of diverse sexual orientation and gender—and particularly those youth of color—are overrepresented among youth experiencing homelessness, as well as across multiple state-based systems[214,264,265]

- **Up to 40% of all youth experiencing homelessness and housing instability are youth of diverse sexual orientation and gender.**
- **Up to one-third of youth in foster care systems are youth of diverse sexual orientation and gender.**
- **Up to one-fifth of youth in the juvenile justice system are youth of diverse sexual orientation and gender.**

Parent or caregiver rejection due to sexual orientation and gender diversity is just one of many reasons for these inequities; other factors such as parental mental health and substance use, poverty, and racism are common drivers of housing instability and system involvement among youth of diverse sexual orientation and gender.

School

LGBTQI+ adolescents may experience a myriad of sexual orientation- and gender-related stressors in the school environment, where they spend a large portion of their time. Despite increasing cultural visibility and acceptance of people of diverse sexual orientation and/or gender identity, the climates of U.S. secondary schools remain generally unsupportive and unsafe for many sexual- and gender-diverse youth, who experience high levels of verbal and physical harassment and assault, sexual harassment, social exclusion and isolation, and other interpersonal problems with peers.[48]

School bullying and victimization is often linked to nonconformity to gender norms.[275] Across racial/ethnic groups, approximately half of all sexual- and gender-diverse students of color were bullied or harassed based on their racial/ethnic identity.[48] Further, sexual- and gender-diverse students of color were at greater risk of experiencing multiple forms of victimization and were more likely to feel unsafe at school than their white sexual- and gender-diverse peers.[48]

This mistreatment has a significant effect on sexual- and gender-diverse adolescents' mental health and well-being. Victimization due to sexual orientation or gender expression is associated with depressive symptoms, low self-esteem, and suicidality,[111,275,276] as is not having access to appropriate bathrooms and feeling unsafe in bathrooms and other school facilities.[277,278,279]

Experiences of victimization and discrimination are also linked to negative academic outcomes among sexual- and gender-diverse youth.[184] Victimization from peers and school staff, combined with discriminatory policies, likely contributes to the over-representation of sexual and gender minorities in the juvenile justice system.[48,279] Sexual- and gender-diverse youth of color, particularly girls, are extremely overrepresented among incarcerated youth.[214,279, 280] Research shows that youth of diverse sexual orientation and/or gender identity are not only more likely to experience exclusionary discipline at school, but also appear to be sanctioned more harshly than heterosexual, cisgender teens for the same behavior and are at an increased risk for juvenile justice involvement.[248,281]

School and peer networks can also be a place where youth of diverse sexual orientation and/or gender identity find support. High levels of support from friends, classmates, and school professionals is associated with better mental health and lower suicidality among youth of

School resources that support the health and well-being of youth of diverse sexual orientation and/or gender identity include:

- **The presence of Gender and Sexuality Alliances (GSAs) or other similar supportive peer networks**
- **Antidiscrimination and antibullying policies that explicitly include sexual orientation, gender identity, and gender expression**
- **Policies that allow youth to use their chosen name, pronouns, and facilities that align with their gender identity**
- **Educators who are trained and accept and support students of diverse sexual orientation and/or gender identity**
- **Inclusive curricula resources, such as including the history of people and families with diverse sexual orientation and/or gender identity, and age-appropriate health curricula that discuss sexual orientation and gender identity.[39,43]**

diverse sexual orientation and/or gender identity.[49] Additionally, when youth have access to high levels of peer or school support, this may reduce the negative impact that experiencing victimization has on their mental health.[276] Friends of diverse sexual orientation and/or gender identity may be of particular importance, because they are more likely to provide support for sexuality- and gender-related stress.[282,283] Many youth of diverse sexual orientation and/or gender identity connect with peers and access social support online that may be unavailable to them in person.[284,285] Online sources of support have become increasingly important for youth of diverse sexual orientation and/or gender identity during the COVID-19 pandemic.[286]

School policies and resources that create an inclusive, safe environment positively influence student behavioral health and well-being.[287,288] Specifically, these school policies reduce substance use and planned suicide and suicide attempts.[287] GSA is a student-led, school-based club that aims to provide a safe space for LGBTQI+ students. "GSA" originally referred to "Gay-Straight Alliance," but many GSAs now use the acronym to refer to "Gender and Sexuality Alliance" to acknowledge the full spectrum of sexual orientation and gender diversity.[289]

Both the presence of and participation in a GSA has beneficial outcomes for sexual- and gender-diverse students and others, including increased feelings of safety, lower truancy, and decreased threats of violence in school.[48,287] School policies associated with improved health and well-being of students of diverse sexual orientation and/or gender identity include:

- Antidiscrimination and antibullying policies that enumerate sexual orientation, gender identity, and gender expression
- Policies that allow youth to use facilities that align with their gender identity and/or that provide gender-neutral facilities
- Policies that allow students to use their chosen name and pronouns[278,279]

Training school staff and educators about how to support youth of diverse sexual orientation and/or gender identity is related to lower suicide attempts among these students when provided.[287] Finally, curricula that are inclusive of students and families of diverse sexual orientation and/or gender identity are associated with beneficial outcomes such as fewer

In the most recent National School Climate Survey of LGBTQ+ youth, the Gay, Lesbian & Straight Education Network (GLSEN) found that:

- **60% felt unsafe**
- **69% were verbally harassed**
- **58% were sexually harassed**
- **26% were physically harassed**
- **11% were physically assaulted**
- **45% were cyberbullied**

60% of students of diverse sexual orientation and gender surveyed experienced policies that are discriminatory based on sexual orientation, gender identity, or gender expression at school. Transgender and gender-diverse students were most likely to report incidences with discriminatory policies and practices, including being prevented from using their chosen name and pronouns, and bathrooms and locker rooms aligned with their gender identity.[48]

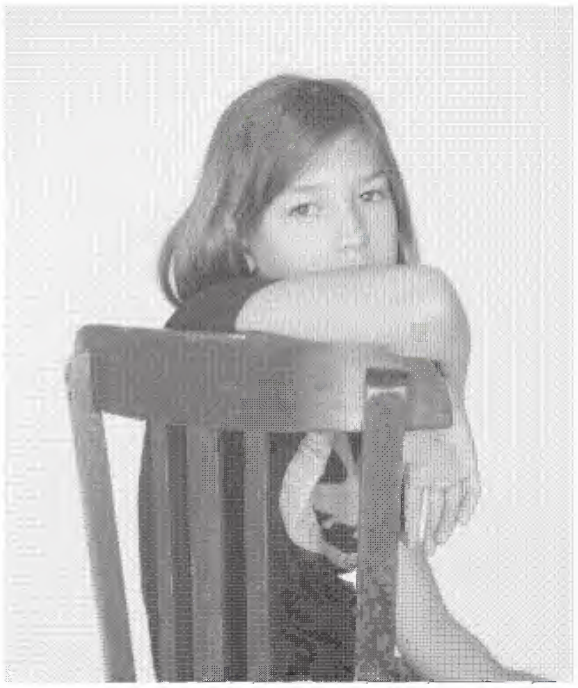
instances of biased language against students of diverse sexual orientation and/or gender identity, students feeling safer, fewer reported instances of victimization, increased peer acceptance, and lower levels of depression; these benefits may be related to the curricula helping to reduce negative stereotypes against LGBTQI+ students.[48] These policies and practices not only are associated with benefits for students of diverse sexual orientation and/or gender identity but also have school-wide beneficial effects across behavioral health and psychosocial outcomes among heterosexual youth.[287]

Community Climate & Policies

Community climate and policies also have an impact on the health and well-being of youth of diverse sexual orientation and/or gender identity. Community climate—defined by the presence or absence of supportive policies, places of worship that are open and inclusive, other LGBTQI+ people, and anti-LGBTQI+ rhetoric—is associated with behavioral health outcomes among LGBTQI+ adolescents. Studies have found that adolescents of diverse sexual orientation and/or gender identity living in areas with a more supportive community climate have better mental health and are less likely to use substances.[290,291]

State and federal laws and policies also affect the health and well-being of sexual- and gender-diverse populations, including youth.[292] More research has been conducted with adults, where supportive and protective policies—such as protection from discrimination in schools and ability to change name and gender on identity documents—have consistently been linked with

better mental health, reduced substance use, and increased access to health care.[205,293,294] Meanwhile, policies that permit discrimination against people of diverse sexual orientation and/or gender identity are linked with poorer behavioral health outcomes.[85] It appears that state and federal laws and policies have a similar effect on youth of diverse sexual orientation and/or gender identity, with the presence of supportive laws and policies associated with reduced suicidality among high school students.[295,296]



Gender Affirmation

In addition to benefiting from gender-affirming support from families, communities, peers, and school professionals as described above, taking desired steps in social transition and access to medical gender transition for those for whom it is medically necessary is associated with better mental health among transgender and gender-diverse youth.[51,67,80,81,155,226,297,298,299,300,301,302,303]

Social transition and medical gender transition are discussed in greater detail in the next section. Improving access to gender affirmation for gender-diverse youth across the various domains of their lives may reduce the mental health inequities seen in this population.

Beneficial Therapeutic Approaches and Interventions in LGBTQI+ Youth and Their Families

Behavioral health professionals provide youth and their families with developmentally sensitive, culturally appropriate, and client-centered interventions that emphasize acceptance, support, and understanding and that match the child and adolescent's cognitive and emotional development.

Appropriate therapeutic approaches with LGBTQI+ youth do the following:

- Provide accurate information on sexual orientation and gender identity and expression.
- Identify sources of distress, including internalized stigma and minority stress, and work with children, adolescents and families to reduce distress experienced by children and adolescents.
- Support adaptive coping to improve psychological well-being.
- Support youth as they learn more about their sexual orientation and gender identity, and supporting families in accessing gender-affirming care for their transgender child when indicated.
- Help children and adolescents navigate their sexual orientation, gender identity, and gender expression within the context of their intersecting identities.

Client-Centered Individual Approaches

Behavioral health providers offer developmentally sensitive, affirmative interventions to youth. Developmentally sensitive approaches account for appropriate developmental emotional and cognitive

capacities, developmental milestones, and emerging or existing behavioral health concerns.

Affirmative approaches recognize and communicate that being of diverse sexual orientation and/or gender identity does not constitute a mental disorder, and that variations in sexual orientation, gender identity, gender expression, and sex characteristics are normal aspects of human diversity, including nonbinary gender identities.[75,304,305,306] Affirmative approaches recognize that when behavioral health issues exist, they often stem from stigma and negative experiences rather than being intrinsic to the child or adolescent.[76] When working with children and adolescents, providers examine not only risk factors but also sources of resilience across the multiple environments that influence the health and well-being of young people.[306]

Effective approaches support youth in identity exploration and development without seeking predetermined outcomes related to sexual orientation, gender identity, or gender expression.[189,305] Key aims are to dispel negative stereotypes and provide accurate information in developmentally appropriate terms for children and adolescents.

Scientists and researchers are constantly discovering more about sexual orientation, gender identity, and expression. For some youth, a focus on identity development and

exploration that allows them the freedom of self-discovery within a context of acceptance and support is vital to improving behavioral health and well-being.[307] It is important to note, however, that identity exploration is not relevant or needed by all youth or a required focus of therapy for youth of diverse sexual orientation and/or gender identity. Additionally, it is important for behavioral health providers to respect what the identity exploration process looks like to each individual. Taking steps in social transition is one way for gender-diverse youth to explore their gender (see "Social Transition" section below).

Practices that attempt to change or prevent youth from identifying as sexual- and gender-diverse or from expressing their sexual orientation and gender identity are harmful and are never appropriate.[10,307] This includes approaches that discourage youth from identifying as transgender or gender-diverse and/or from expressing their gender identity. Sometimes these are misleadingly referred to as "exploratory therapy." Additionally, providers support youth in age-appropriate tasks, such as integrating sexual orientation and gender identities with other identities, safely navigating coming out or sharing their identities with others, and fostering positive relationships with caregivers, families, and peers.[79,307]

Exposure to laws and policies that do not support youth of diverse sexual orientation and/or gender identity, and other negative experiences, including bullying and family rejection, drive risk for certain behavioral health concerns among these youth.[55,308,309] Behavioral health providers should assess for ACEs, other family rejecting behaviors, additional experiences of victimization, trauma-related disorders, and suicidality, and be prepared to address these concerns with LGBTQI+ youth in treatment. Appropriate interventions may aim to reduce or remove stressors a child or adolescent is experiencing that are associated with poor behavioral health. Alternatively, interventions may aim to change the cognitive, affective, and behavioral ways that youth of diverse sexual orientation and/or gender identity react to these stressors.[214]

Several cognitive behavioral therapy (CBT) interventions for youth of diverse sexual orientation and/or gender identity have been developed, including EQuIP,[310] AFFIRM,[311] and Rainbow SPARX.[312] LGBTQ-affirmative CBT appears to be particularly efficacious for Black, Latino, and Asian American and Pacific Islander young people of diverse sexual orientation and/or gender identity, potentially because the focus on stressors may also help young people of color navigate stressors related to being a racial/ethnic minority.[214,313] There is also evidence supporting the use of mindfulness-based coping for sexual orientation-related school-based victimization.[314] Evidence-based trauma-focused interventions designed for youth of diverse sexual orientation and/or gender identity and their families can reduce symptoms of past trauma and enhance coping and well-being.[315]

Behavioral health providers should be aware of and share crisis services specific to LGBTQI+ youth, local resources for LGBTQI+ youth, and online platforms where LGBTQI+ youth can find affirming social connections and support. Given the increased rates of suicidality seen among youth of diverse sexual orientation and/or gender identity, LGBTQI+ crisis services, such as those provided by The Trevor Project are vital. The Trevor Project offers direct suicide and crisis intervention services for LGBTQI+ youth by phone, text, or online chat.[214,316]

Behavioral health providers should be aware of available community resources that support LGBTQI+ youth and their families, such as local

LGBTQI+ community centers, GSAs in schools, and support groups for youth and/or their caregivers, as well as online platforms. In addition to crisis services, The Trevor Project provides a safe social-networking community for LGBTQI+ youth and their friends and allies. This online platform became even more critical during the pandemic because it allowed youth to find affirming connections even when physically isolated. PFLAG, which is the largest organization in the United States focused on providing support, education, and advocacy for LGBTQI+ people and their loved ones and has more than 325,000 members with hundreds of local chapters. PFLAG can serve as another resource of support for LGBTQI+ youth and their families.[317]

Behavioral health providers should describe their treatment plan and interventions to children, adolescents, and their parents and families to ensure they understand the goals, potential benefits, and any risks of treatment. Behavioral health providers should obtain informed consent with all parties—including minors—for treatment, and should always involve parents and caregivers in decisions about a minor's care if the minor is not old enough to legally give consent.[318] When obtaining informed consent/assent, it is important to be aware of and attend to power dynamics between parents/caregivers and youth, as well as between the provider and youth. Interventions that attempt to change sexual orientation, gender identity, or gender expression, or any other form of SOGI change efforts are inappropriate and can cause significant harm. Informed consent/assent for clinical care would include ensuring understanding of various components, including associated risks, expected benefits, and alternative treatment options; therefore, by definition, informed consent/assent cannot be provided for an intervention known to cause

significant harm and does not have any known benefit to the client.[319]

Family Approaches

Wherever it is safe to do so for the child, parental and caregiver involvement is an important part of supporting LGBTQI+ youth. Parental and caregiver attitudes and behaviors play a significant role in the adjustment of children and adolescents. Parent and caregiver distress may be the cause of a referral for treatment.[24,102,258] Reducing family rejection, hostility, and violence (verbal or physical), and increasing family acceptance and support, contributes to the mental health and safety of the child and adolescent.[53,102,258,320]

Interventions that increase family and community support and understanding while decreasing rejection directed at LGBTQI+ youth are recommended for families. Behavioral health providers supply family members with accurate, developmentally appropriate information regarding diversity in sexual orientation and gender, and strive to dispel myths regarding the lives, health, and psychological well-being of individuals of diverse sexual orientation and/or

gender identity.[304,307] Family therapy that provides anticipatory guidance to parents and caregivers about the significant mental health risks caused by rejection of their child's sexual orientation and gender identity is vital.[102,258] Understanding and addressing parent and caregiver concerns regarding current or future sexual orientation and gender identity is important. Further, behavioral health providers can attempt to help families and caregivers modify rejecting behaviors by explaining the link between family rejection and negative health problems, identifying rejecting and accepting behaviors, and providing recommendations for increasing supportive behaviors on the part of the family.

Some affirming approaches to family therapy that include youth of diverse sexual orientation and/or gender identity aim to demonstrate how family members' identities—such as their race and ethnicity, immigration, socioeconomic status, and more—affect their ability to understand and support their youth.[321,322] Attachment-based approaches to family therapy have been used with suicidal sexual minority adolescents.[323] Trauma-focused CBT is an evidence-based treatment for trauma-impacted youth aged 3 to 17 and their parents or primary caregivers. This intervention has been adapted for use specifically with youth of diverse sexual orientation and/or gender identity by integrating the treatment framework with the Family Acceptance Project.[315]

Family therapists and researchers often focus on reframing family concerns—even their disapproval and rejection of sexual orientation and gender diversity—as a manifestation of care and love and focus on teaching non-rejecting ways to communicate those positive emotions. For example, providers can help the family create an atmosphere of mutual respect as a natural extension of seeing each person as having intrinsic worth.[324] This can help ensure the safety of each person from being hurt or bullied in the home. This communicates an important message to a young person that their safety is important to the provider and to the family. Eventually, this mutual respect and

support can be extended to other settings, such as neighborhoods, community institutions, and schools. Safety in this context is not only physical safety, but also emotional safety.[324]

Behavioral health providers may wish to increase their own competence in working with communities with diverse values and beliefs, and focus on viewing these values and beliefs with humility and mutual respect.[325] This includes understanding how to translate between psychology and deeply held values rather than judging those beliefs. Certain language, such as acceptance and/or affirmation, might not resonate with some communities, whereas the concept of unconditional love might.[324]

Many parents and caregivers must also navigate their own process of "coming out" and resolve fears of discrimination or negative social reactions if they disclose their child's sexual- and gender-diverse identity within their communities, at work, and to other family members.[326] Parents and caregivers often have fears for their child's emotional and physical safety, among other worries for their future.[37,327] Behavioral health providers can help parents plan in an affirmative way for the unique life challenges that they may face as parents of an LGBTQI+ child.

Further, behavioral health providers can address other stresses, such as managing life celebrations and transitions and coping with feelings of loss, and aid parents in advocating for their children in school situations—for example, when they face bullying or harassment. Groups for multiple families led by behavioral health providers, as well as online groups or forums for parents and caregivers of LGBTQI+ children and adolescents, may be helpful to build connections and share resources.[328]

Additional Approaches With Gender-Diverse Youth

Social Transition

Social gender transition refers to living daily life in line with one's gender identity, and the processes by which a child or adolescent is acknowledged by others as this gender.[39,40] Social transition can include a range of gender-related changes that individuals may make, and often includes adopting a name, pronouns, and clothing consistent with one's gender identity.[35,39,40] There is no one way or right way to socially transition. Transgender and gender-diverse youth may seek out social transition at different ages and stages of development.[34] Social gender transition does not require assessment or intervention from health professionals. However, providers can help families protect children's safety, ensure emotional, psychological, and social well-being, and help children and families navigate possible complexities of exploring and taking steps in social transition.[80]

Taking steps in social transition allows youth the ability to explore and make meaning of how they experience their gender, which is an important

Gender affirmation, including social transition (e.g., changing one's name, pronoun, and/or appearance) and gender-affirming medical care, is appropriate and beneficial for many gender minority children and adolescents. Based on the individual child's or adolescent's needs, gender-affirming medical care may be medically necessary. Withholding timely gender-affirming care when indicated, withholding support for a gender-affirming exploratory process, and/or withholding support of social transition when desired, can be harmful. These actions may exacerbate and prolong gender dysphoria.

part of developing a positive identity and sense of self. For some youth, desires for their name, pronouns, and appearance continue to change and evolve over time; for others, these remain stable over time.[35,39,40] For gender-diverse children who want to socially transition, social transition appears to serve a protective function and contribute to positive mental health and well-being.[51,67,78,229]

Given this, experts increasingly agree that children should not be denied the opportunity to explore and/or express their gender through social transition steps when desired by the child.[75,185,186,329] The possibility that a children's gender identity can be dynamic and may change over time should not be used as a justification to restrict a child from taking social transition steps. Children should be affirmed in how they currently identify and express their gender and be supported throughout their development and exploratory process, including the potential for future changes in how they identify and express their gender.[180,185,186] Behavioral health specialists in pediatric gender care can offer psychosocial support, insights, and guidance regarding the appropriateness of gender-related needs of gender-diverse children at different developmental stages.[25]

Withholding support for a gender-affirming exploratory process and/or for social transition when desired, can be harmful because those actions may exacerbate and prolong gender dysphoria.[78,299,329] At the same time, parents and caregivers may have valid concerns about reactions from others, including bullying and safety. When weighing factors related to social gender transition, concerns related to social transition should be weighed against the risks of not affirming a child's experienced gender, including increased distress or feelings of dysphoria, social isolation, depression, or suicide due to lack of social support.[29] Whether or not a child socially transitions or desires to, behavioral health providers can help explain to parents and caregivers how gender development is dynamic for some but not all children and highlight the importance of being open to and accepting of the possibility that their youth may remain stable in their feelings or may desire to make changes again in the future.[305]

Medical Gender Transition

Gender-affirming medical care is often medically necessary for individuals with a diagnosis of gender dysphoria, and can refer to a range of evidence-based interventions provided in consultation with licensed medical providers. Such care is defined here as a care plan or service that is necessary to assess, maintain, or improve health and well-being and to avoid illness or reduce symptoms based on existing professional guidelines and scientific evidence. The appropriateness of medical interventions varies by the individual's age, developmental stage, and experience of dysphoria, and decisions about providing gender-affirming care are reached with the involvement of an adolescent's parent or legal guardian.[332] No medical interventions are currently undertaken

Gender-Affirming Care: A specialized model of care used in the treatment of gender dysphoria that uses evidence-informed treatment options to promote patient health and prevent the risk of poor mental and physical health outcomes.[330,331] Not all youth need to undergo medical intervention; indeed, this is often not the case. Gender-affirming care is highly individualized and focuses on the needs of each individual by including psychoeducation about gender and sexuality (appropriate to the age and developmental level).

or recommended for gender-diverse children before the initial onset of puberty.[74,75] Gender-affirming medical care, including both pubertal suppression and hormone therapy, has proven effective in improving the well-being of young transgender and gender-diverse adolescents both during and well after initiation of treatment.[81,82,156,296,297,298,299,300,302,303,333]

Recent research indicates that gender-affirming care has a positive impact on mental health. Current professional guidelines provide information on the appropriate application of gender-affirming care interventions.[25] It is widely held that withholding gender-affirming care for an adolescent who needs this care is detrimental to their mental health.[77,186] Withholding timely gender-affirming care when indicated may cause harm by exacerbating and prolonging gender dysphoria.[83,84]

Behavioral health providers play an important role in educating adolescents and their parents, caregivers, and supporting families on this information as well as in assessing their understanding so that they can give full informed consent and assent.[187,334] This education includes information on:

- Various options for medical gender transition
- Up-to-date information about the effects of treatment
- Benefits on well-being
- Potential side effects

The support of a behavioral health provider during these processes can aid adolescents in identifying care needs, adjusting to their changing physical characteristics, and navigating responses from people in different aspects of their lives. Continued mental health care should be offered when an adolescent's gender care needs require continued affirming exploration and/or when other psychological, psychiatric or family problems exist. Given that pubertal suppression or administration of hormone therapy occurs over many years during important developmental periods, the need for behavioral health care, and type of behavioral health intervention needed, may change with time as new questions arise.[335] Transgender and gender-diverse youth, like all youth, should have the option to access psychological treatment if they choose. However, if there are no concerns, this may not be necessary.

For additional information and guidance related to youth and medical gender transition, see "Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents" from the American Academy of Pediatrics[76] and the most recent guidelines from the World Professional Association on Transgender Health (WPATH; www.wpath.org).[25]

Future Directions for Research

As recommended by the U.S. Surgeon General in the 2021 report *Protecting Youth Mental Health*, future research must prioritize data and research with youth populations who are at-risk for adverse mental health outcomes.[336] This includes LGBTQI+ youth broadly, as well as LGBTQI+ youth who are also racial/ethnic minorities, have experienced poverty during childhood, have disabilities/different abilities, and are involved in child welfare or juvenile justice systems. Areas of opportunity for future research, as well as the validity and quality of existing research, are discussed in several sections of this report. Methodologically rigorous peer-reviewed research is vital to improving our understanding of the complexities of sexual orientation and gender among children and adolescents. Several potential areas for future research are identified below.

Documenting Sexual Orientation and Gender Diversity in Youth

To better understand the experiences and needs of LGBTQI+ youth, research focused on youth in the general population should regularly assess sexual orientation, gender identity, and gender expression as demographic indicators. Given the expansive range of descriptive identity terms that people today use to describe their sexual orientation and gender (e.g., pansexual, asexual, nonbinary, gender queer), asking about sexual orientation and gender in ways that include these identities and provide an option for open-ended responses will ensure that LGBTQI+ youth are appropriately included and represented in research.

Development of Sexual Orientation and Gender Identity

There remains much to learn about the development of sexual orientation and gender identity in youth. Basic research on the developmental pathways of these identities is necessary. How these identities are embedded in cognitive and emotional development and other developmental processes would aid in the understanding of human development as well as developing and refining appropriate interventions to support behavioral health. Such research must be inclusive of nonbinary identities. To better understand the various developmental trajectories of gender-diverse youth, prospective, longitudinal studies that follow gender-related development of youth over time are needed.

Culturally Specific Mitigation of Distress Relating to Sexual Orientation, Gender Identity, and Gender Expression

SOGI change efforts are harmful practices that are never appropriate with LGBTQI+ youth, and efforts are needed to end these practices. Families experiencing conflict related to their youth's sexual orientation, gender identity, and gender expression need access to alternative interventions to mitigate this distress that are appropriate and beneficial for youth and families. More targeted research that acknowledges the intersections of identity, including race, ethnicity, culture, faith, and socioeconomic status could shed light on positive, appropriate, whole-family therapeutic approaches to addressing these issues.

Researchers should evaluate these practices and integrate them into behavioral health care. Researchers should also work collaboratively with young people and families from faith communities to better understand the interplay between values and traditions and the safety and well-being of LGBTQI+ youth. The work of the Family Acceptance Project, cited in this report, speaks to the necessity of an increased focus on approaches specific to various communities, including those that are culturally and religiously diverse. These include conversations about sexual orientation, gender identity, and gender expression and how to support LGBTQI+ youth in culturally congruent ways.

Addressing Health Inequities Within LGBTQI+ Youth Populations

LGBTQI+ youth experiencing homelessness, in juvenile justice facilities, or otherwise in out-of-home care may lack permanent and stable family connections in part because of family distress or rejection relating to their LGBTQI+ identity. These vulnerable populations, as well as low-income and racial and ethnic minority LGBTQI+ youth, are often neglected in research studies that most often recruit youth who are already connected to clinics or providers. Future researchers interested in research with sexual- and gender-diverse youth should address this need for more representative sampling and better recruitment efforts.

Building Resilience and Promoting Health and Well-Being

Beyond ending harmful practices with LGBTQI+ youth and addressing health inequities, more research is needed that focuses on the ways LGBTQI+ youth are thriving. Greater understanding is needed of the factors that contribute to resilience and positive behavioral and physical health outcomes among LGBTQI+ youth, as is an increased focus on the development, evaluation, and dissemination of health-promoting interventions. Research using participatory methodologies to collaborate with LGBTQI+ youth to identify their needs, priorities, and ideas for intervention strategies is vital to increase the relevance, quality, and impact of research and interventions with this population.

Long-Term Outcomes

More research would be beneficial to further explore the developmental trajectories of sexual orientation, gender identity, and gender expression. Additionally, future research could focus on better understanding the long-term medical and behavioral health outcomes associated with early experiences of family and community distress due to sexual orientation and gender identity and expression. Other recommended areas of opportunity for longitudinal research include:

- Long-term outcomes from early social transition and pubertal suppression
- Rigorous evaluation of current practices and protocols, including affirmative models, structural interventions, and culturally specific models
- Harms associated with laws and policies that bar youth from participating at school or in extracurricular activities in a way that is consistent with their gender identity
- Prospective research focusing on younger children, in partnership with pediatric clinics, schools, and other community-based institutions
- Methods of supporting positive behavioral health for LGBTQI+ youth, including building resiliency against suicidality, self-harm, risky behaviors, depression, anxiety, substance use, and other behavioral health issues

Integration, Collaboration, and Dissemination

Researchers and clinicians should examine and evaluate the best methods for integrating and disseminating best and promising practices for addressing sexual orientation and gender identity and expression among youth, and how to successfully collaborate with parents, guardians, caregivers, providers, and community leaders. This could include conducting research with these populations focused on knowledge, attitudes, and beliefs relating to efforts to change sexual orientation, gender identity, or gender expression.

Finally, the behavioral health community can work to support community-based organizations to develop common ground and consensus on these topics to promote health and well-being within youth populations. This might include:

- Support for LGBTQI+ youth programming and services across the country
- Outreach to parents, caregivers, and families with accurate information about supporting LGBTQI+ youth's behavioral health
- Inclusion of LGBTQI+-specific questions in national behavioral and mental health surveys

Section 3: Policy Approaches to Support the Behavioral Health and Well-Being of LGBTQI+ Youth

Introduction and Foundational Principles[1]

Moving from evidence to action necessitates scientifically grounded public policies. This section focuses on selected policy levers that aim to improve the behavioral health of LGBTQI+ youth.

U.S. Department of Health and Human Services (HHS) policy priorities for improving the mental health of and reducing substance use by LGBTQI+ youth are based on efforts to ensure LGBTQI+ civil rights and to increase access to, affordability of, and equity in health care. Such policies include implementation of the June 15, 2022, Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals,[14] the January 20, 2021, Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,[15] and the January 20, 2021, Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.[337]

HHS policies include protection against discrimination based on sexual orientation and gender identity as found in the Affordable Care Act (ACA).[338] HHS also has other policies and programs specific to nondiscrimination on the basis of sexual orientation and gender identity.[339,340] For example, HHS issued a Notice of Proposed Rulemaking related to Section 1557 of the ACA, to further prevent discrimination on the basis of sexual orientation and gender identity.[341]

To further strengthen protections for LGBTQI+ youth, their parents, and caregivers, on March 2, 2022, HHS Secretary Xavier Becerra issued a statement reaffirming HHS efforts to support and protect LGBTQI+ youth and assist their parents, caretakers, and families in accessing gender affirming care.[342]

SOGI change efforts are inappropriate practices that should not be provided to children or adolescents.

A Memorandum issued by the Children's Bureau at the Administration for Children and Families for child welfare professionals and healthcare providers aims to protect LGBTQI+ youth.[343] HHS has also issued guidance stating that denying health care based on gender identity or restricting doctors and healthcare providers from providing care because of a patient's gender identity may constitute prohibited discrimination.[344]

The following key policy areas have been identified by the federal government, researchers, and advocates:

- End harmful and ineffective efforts such as sexual orientation and gender identity (SOGI) change efforts.
- Ensure access to evidence-based care.
- Promote behavioral health by strengthening nondiscrimination policies.

[1] All statements in text boxes are Consensus Statements provided in Section 1 of this document.

- Improve behavioral health through support from families, schools, and communities.
- Advance research that improves care.

Ending Sexual Orientation and Gender Identity Change Efforts

SOGI change efforts are ineffective and harmful to children and adolescents (see Sections 1 and 2). The continued practice of these efforts puts LGBTQI+ youth at risk of significant harm and prevents them and their families from receiving appropriate evidenced-based behavioral health care that is consistent with existing professional guidelines.

Based on scientific evidence and broad professional and scientific consensus, many federal, state, and local governments have taken steps to regulate and eliminate the practice of SOGI change efforts directed at children and adolescents. These efforts include legislative bans, executive orders, and pathways to civil court claims alleging consumer fraud, among others.

Several bills and resolutions have been introduced in Congress in the past decade to discourage SOGI change efforts or to require nondiscrimination in the provision of behavioral health services to sexual- and gender-diverse youth. This legislation would ban federal funding, encourage state bans, or define SOGI change efforts as consumer fraud.

On June 15, 2022, the Biden Administration issued the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals.[14] It includes a charge to HHS to take steps to end SOGI change efforts in the United States, by exploring guidance for federally funded programs, supporting provider training and technical assistance, and providing public information about harms and alternatives.

At the state level, as of January 2023, 20 states and the District of Columbia have passed laws to protect minors from the practice of SOGI change efforts. An additional six states and one territory have partial bans.[345] These laws bar behavioral health providers from practicing SOGI change efforts with minors. Some states provide protections for vulnerable adults, impose restrictions on the use of state and federal funds, and offer consumer protection provisions. At the local level, about 90 municipal and county governments prohibit SOGI change efforts.[346]

Advocates have suggested federal, state, and local policy efforts to end SOGI change efforts that include the following:

- Legislative restrictions on the use of federal or state funding for SOGI change efforts by state health programs (including Medicaid funds), by recipients

of such funding, or through health insurance reimbursements (see for example, H.R. 2328, "Prohibition of Medicaid Funding for Conversion Therapy Act" from the 117th Congress).[347]

- Policies that prohibit SOGI change efforts with minors receiving care in programs that receive federal funds to serve youth, such as community mental health centers, and juvenile justice, child welfare, and foster care programs.
- Clarification that existing nondiscrimination policies prohibit the practice of SOGI change efforts with minors. These legal claims of discrimination have been based on the theory that providing this ineffective and harmful therapy is due solely to an individual's sexual orientation or gender identity.

In addition to federal and state legislative and regulatory action, consumer protection laws have been suggested as a mechanism for ending the use of SOGI change efforts. This strategy extends beyond prohibiting change efforts by behavioral health professionals to affect any commercial act (for a fee), including those by unlicensed practitioners and groups.

These efforts derive from a civil action in which a New Jersey court ruled in 2015 that an organization's sexual orientation change efforts program violated the state's consumer fraud law through multiple misrepresentations.[348] The Court ruled as a matter of law that scientific evidence demonstrated that being gay, lesbian, or bisexual was not a mental disease or disorder and could not be changed. Thus, the Court found that a fraudulent misrepresentation was made every time an individual accepts payment for sexual orientation change efforts because being gay, lesbian, or bisexual is not a disease and cannot be "cured." The Court awarded the plaintiffs financial compensation and prohibited the organization from providing sexual orientation change efforts.[348]

Available research indicates SOGI change efforts can cause significant harm. Available research indicates that these efforts are not effective in altering sexual orientation; no available research indicates that they are effective in altering gender identity. No available research supports the claim that SOGI change efforts are beneficial to children, adolescents, or families.

Efforts to protect consumers through consumer protection laws have been taken at the federal and state levels. At the federal level, the Biden Administration is encouraging the Federal Trade Commission (FTC) to consider whether SOGI change efforts are an unfair and deceptive practice and whether to issue consumer warnings or notices. Additionally, in the 117th Congress, bills were introduced that define SOGI change efforts as unfair or deceptive acts or practices under the jurisdiction of the FTC Act (Therapeutic Fraud Prevention Act of 2021; HR.4146 and S.2242). Some advocates believe that the FTC can act even without new legislation. In 2016, a complaint was filed with the FTC alleging fraudulent misrepresentation by a group that advertises change efforts.[349,350]

At the state level, Illinois passed a ban on SOGI change efforts with minors (Illinois Public Act 099-0411).[351] The law specifies that advertisements for sexual orientation change efforts that represent being gay, lesbian, or bisexual as a disease or disorder for minors and adults is a violation of the state's consumer fraud and deceptive business act. As of January 1,

2023, jurisdictions banning SOGI change efforts with minors included California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Utah, Vermont, Virginia, and Washington. Additionally, jurisdictions with partial bans on SOGI change efforts included Michigan, Minnesota, North Carolina, North Dakota, Pennsylvania, Puerto Rico, and Wisconsin.[345]

Ensuring Access to Evidence-based Care

Beyond ending harmful practices such as SOGI change efforts, it is vital that LGBTQI+ youth have access to evidence-based care. Removing limits to appropriate care is multifaceted and may vary based on multiple factors, including other health inequities such as those based on income and race/ethnicity, among others. Policy levers to improve access include:

- Preventing bans on gender-affirming care
- Improving access to gender-affirming care in health plan benefits across all payors
- Ensuring LGBTQI+ youth can access appropriate care and support in child welfare programs
- Increasing professional training and education to improve access to and quality of behavioral health care especially for gender-diverse and transgender youth

Preventing Bans on Gender-Affirming Care

Gender-affirming care is supported by extensive research, and based on the individual child's or adolescent's needs, may be medically necessary. Evidence has demonstrated mental health benefits associated with receipt of gender-affirming care, such as reduced depression and decreased risk for suicide. Withholding timely gender-affirming care when indicated, withholding support for a gender-affirming exploratory process, and/or withholding support for social transition when desired can be harmful.[25,352,353,354] However, some states have introduced or passed laws that ban access to this medically necessary care.[107,355]

Policies that seek to categorically ban gender-affirming medical care or penalize providers, parents, and caregivers who provide or seek gender-affirming medical care pose serious risks.[353,354] Prohibitions on or penalties for providing or seeking out medically necessary and therapeutically indicated best practices place behavioral health and medical providers and parents and caregivers in situations that conflict with evidence-based professional guidelines, ethics, and standards.[354] Lack of access to such care poses serious behavioral health risks to youth of diverse sexual

Groups that have stated opposition to policies that limit access to or ban appropriate gender-affirming care include American Academy of Child and Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Medical Association, American Osteopathic Association, American Psychiatric Association, American Psychological Association, Endocrine Society and Pediatric Endocrine Society, U.S. Professional Association for Transgender Health, and World Professional Association for Transgender Health.[106,356,361]

orientation and/or gender identity and their families, parents, and caregivers, such as an increased risk of suicidal ideation, depression, and trauma.[107,343,353,354,356]

As noted above, the Biden Administration has taken multiple steps to improve behavioral health care by ensuring access to medically necessary and evidence-based care for LGBTQI+ youth. This includes policies to address state restrictions in such care. For example, the June 15, 2022, Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals includes a charge to HHS to ensure that LGBTQI+ youth and their families have access to medically necessary care including mental health care, consistent with applicable law.[14]

HHS has taken steps to maintain access to evidence-based care, especially for transgender youth. HHS has provided child welfare professionals, healthcare providers, and states and localities with information on the federal protections that exist to ensure that civil rights are protected and LGBTQI+ youth receive medically necessary and evidence-based care.[343,344]

As an example of efforts to maintain access to evidence-based care, the U.S. Department of Justice (DOJ) intervened in a federal lawsuit challenging a recently enacted Alabama law, Senate Bill (S.B.) 184, that makes it a felony to cause or provide gender-affirming care to transgender youth under the age of 19.[357,358] In May 2022, the court issued a preliminary injunction preventing the law from being enforced Additionally, the DOJ filed a statement of interest and amicus brief in a case challenging an Arkansas law banning gender-affirming care.[357,359]

State bans on gender-affirming care are unlike laws banning SOGI change efforts. Legal bans on SOGI change efforts are consistent with existing professional guidelines and resolutions and prohibit potentially harmful efforts while permitting behavioral health providers to deliver evidence-based care to LGBTQI+ youth. Numerous professional associations and experts have spoken out against laws or other government actions that limit access to, penalize, or ban appropriate gender-affirming care (see text box).

Improving Access to Behavioral Health and Gender-Affirming Care

LGBTQI+ youth and adults face serious barriers to accessing behavioral health care as well as gender-affirming care. Access to care is especially limited for gender-diverse youth and their families who seek gender-affirming care.[360] The Federal Government and many states have taken steps to reduce barriers to gender-affirming care, improve behavioral health equity, and reduce healthcare discrimination. Several federal and state laws have been interpreted to or expressly prohibit insurance discrimination based on SOGI.

The Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals makes family counseling and support of LGBTQI+ youth a public health priority.[14] This Executive Order charges HHS to seek ways to increase the availability of such family counseling and support programs in federally funded, human services, and child welfare programs among other actions.

Aligned with the Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,[15] HHS issued a Notice of Proposed Rulemaking in July 2022 related to Section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, disability, or age in

certain health programs and activities. The Proposed Rulemaking would codify protections against discrimination on the basis of sex as including discrimination on the basis of sexual orientation and gender identity, which is consistent with the Supreme Court's decision in *Bostock*.[341] This type of federal policy addressing sex, sexual orientation, and gender identity nondiscrimination can help mitigate gaps in state protections.

Almost half of all states prohibit the exclusion of gender-affirming care by private health insurance plans subject to state oversight.[362] Other state laws include protections against discrimination in private health insurance by expressly prohibiting discrimination based on sexual orientation and gender identity.[362,363,364] Experts have also suggested that states and localities provide such benefits to their own employees and dependents and, while almost half have such protections, many do not.[365]

Research on health coverage in private insurance and federal and state health financed programs indicates that youth and adults might not have access to comprehensive gender-affirming care or in-network providers with LGBTQI+ expertise.[247,360,362,363,364,366,367,368,369,370] Consequently, experts have suggested that legislative and regulatory steps be taken to ensure that all such plans reimburse medically necessary treatment for LGBTQI+ individuals of all ages, including gender-affirming care.[365,370]

One way to improve treatment options is through state initiatives, such as explicitly including gender-affirming care as a covered service in the state's benchmark plan in individual and small group market plans. In 2021, the Centers for Medicare & Medicaid Services (CMS) approved Colorado's expansion of the Essential Health Benefit (EHB) benchmark plan that aims to improve access for client-centered gender-affirming care.[368] This change to the EHB benchmark plan aims to expand access to a wider range of services for transgender individuals in addition to benefits already covered. The state is also expanding covered services in the state benchmark plan to include mental wellness exams, which will help all individuals not only those who are LGBTQI+.[369]

Training and Education to Improve Care

A key priority is to expand the number of behavioral health providers who have the expertise to work with LGBTQI+ children, youth, and their families. Research indicates that only a small percentage of gender-diverse youth seeking transition medical services receive them as minors.[366] One aspect of this problem is the lack of behavioral health providers with training and expertise in this area.

Federal Government initiatives have expanded education and training opportunities and the June 15, 2022, Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals charges HHS with providing training and technical assistance in promising evidenced-based care, including mental health care.[14] The SAMHSA Center of Excellence on LGBTQ+ Behavioral Health Equity provides training and consultation for a variety of behavioral health providers.[371] Scientific associations have developed resources and practice guidelines on treatment of LGBTQI+ children, adolescents, and adults that are useful for professional education and practice (see Appendix C).

Several training programs offer education to a wide variety of providers working with LGBTQI+ youth and their families.[371] These trainings can continue to be expanded to improve professional competence in providing services to this population. For example, APA Division 17 (Counseling Psychology) Special Task Group Making Room at the Table: Trans/Nonbinary Pipeline to Counseling Psychology developed "*A Resource for Incorporating Trans and Gender-Diverse Issues in Counseling Psychology Curricula*."[372]

National and state professional associations, including HHS grantees, also maintain webpages with training information on LGBTQI+ issues, including postgraduate and peer education resources.[372,373] Such programs could also expand specialty workforce training opportunities in pediatric and LGBTQI+ concerns across the professional lifecycle from graduate student to seasoned practitioner.

Given the diversity within children, adolescents, and their families, trainings that recognize differences in culture, ethnicity, geography, race, and other factors are critical for effective behavioral health treatment. Increasing cultural responsiveness is especially important to address unique stressors and behavioral health inequities within the sexual- and gender-diverse community, especially in communities of color.[199,374]

Behavioral health providers with competence in the related aspects of religion, spirituality, and sexual- and gender-diverse issues could assist families and individuals in reducing identity and family conflicts that can arise.[374,375,376,377,378,379,380,381] Linkages among community institutions, professional and scientific groups, behavioral health providers, and LGBTQI+ groups that are respectful and open can improve therapeutic services for LGBTQI+ youth and families. One possibility includes collaborations among behavioral health and community leaders and professionals in gender-affirming care to increase understanding about clients from a variety of cultural traditions.[382] Providing education in universities and educational facilities attuned to diverse communities may be a start to initiating dialogue and improving care. Some success has been achieved with dialogues seeking common ground between scientists and such groups rooted in common goals such as child health and optimal child development.[382,383]

Improving Behavioral Health through Antidiscrimination Policies

Youth of diverse sexual orientation and/or gender identity are negatively affected by policies that sanction or sustain discrimination based on sexual orientation and gender identity,[2] even increasing the risk of suicide,[59,292] Although stigma and discrimination can lead to behavioral health concerns, poor behavioral health is not inherent to sexual and gender minorities. Additionally, exposure to school-based bullying and exclusion based on sexual- and gender-diverse prejudice has an adverse impact on the behavioral health of school-aged

Policies that stigmatize, restrict, or exclude gender minority youth are harmful to children and adolescents.

youth.[48,384,385] Transgender and gender-diverse youth face additional discrimination and disadvantage due to the longstanding stigma toward gender-diverse individuals.[356] However, appropriate protections from discrimination allow individuals of diverse sexual orientation and/or gender identity of all ages to thrive.[194,213,355]

Important scientific research indicates that policies that reduce discrimination and advance equal rights have positive effects on behavioral health. Research studies indicate that enacting protective policies that safeguard individuals from discrimination and violence lead to improved physical and mental health for sexual- and gender-diverse youth and adults.[211,386,387,388] Federal and state laws that equalize civil rights and the status of LGBTQI+ individuals are linked to the improved behavioral health noted above. Some states require health insurance plans to cover gender-affirming care and include protections against discrimination in private health insurance by expressly prohibiting discrimination based on sexual orientation and gender identity.[362]

Steps have been taken at the federal, state, and local levels to expand equalizing policies. At the federal level, the Biden Administration has issued important Executive Orders, memoranda, and public statements to reduce discrimination toward individuals with diverse sexual orientations and/or gender identities and support LGBTQI+ civil rights.[14,338,342,343,389,390,391] In the 117th Congress, The Equality Act (H.R. 5) was introduced and would have explicitly prohibited discrimination toward LGBTQI+ individuals.[392] Some states have adopted antidiscrimination and antibullying policies and expanded benefits for LGBTQI+ state employees.[393] State efforts have also included:

- Bans on discrimination by state-licensed healthcare providers
- Bans on SOGI change efforts
- Nondiscrimination laws based on sexual orientation and gender identity
- Supports for same-sex families
- Antibullying laws
- Inclusive curriculum in schools

Local governments have also taken steps to reduce bias and discrimination based on sexual orientation and gender identity and expand protective policies at the local level.[365]

Improving Behavioral Health Through Support for Families, Caregivers, Schools, and Communities

Research summarized earlier in this report indicates that families, schools, and communities contribute to the behavioral health of LGBTQI+ youth. Efforts can facilitate positive behavioral health by providing a climate of support and acceptance. Families, schools, and communities can undermine behavioral health through rejection or discrimination, which have adverse health effects. Policies that increase the dissemination of resources to families, communities, and schools to encourage support and acceptance of LGBTQI+ youth is a high priority. For example, the June 15, 2022, Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals includes initiatives that aim to increase such family counseling and information.[14]

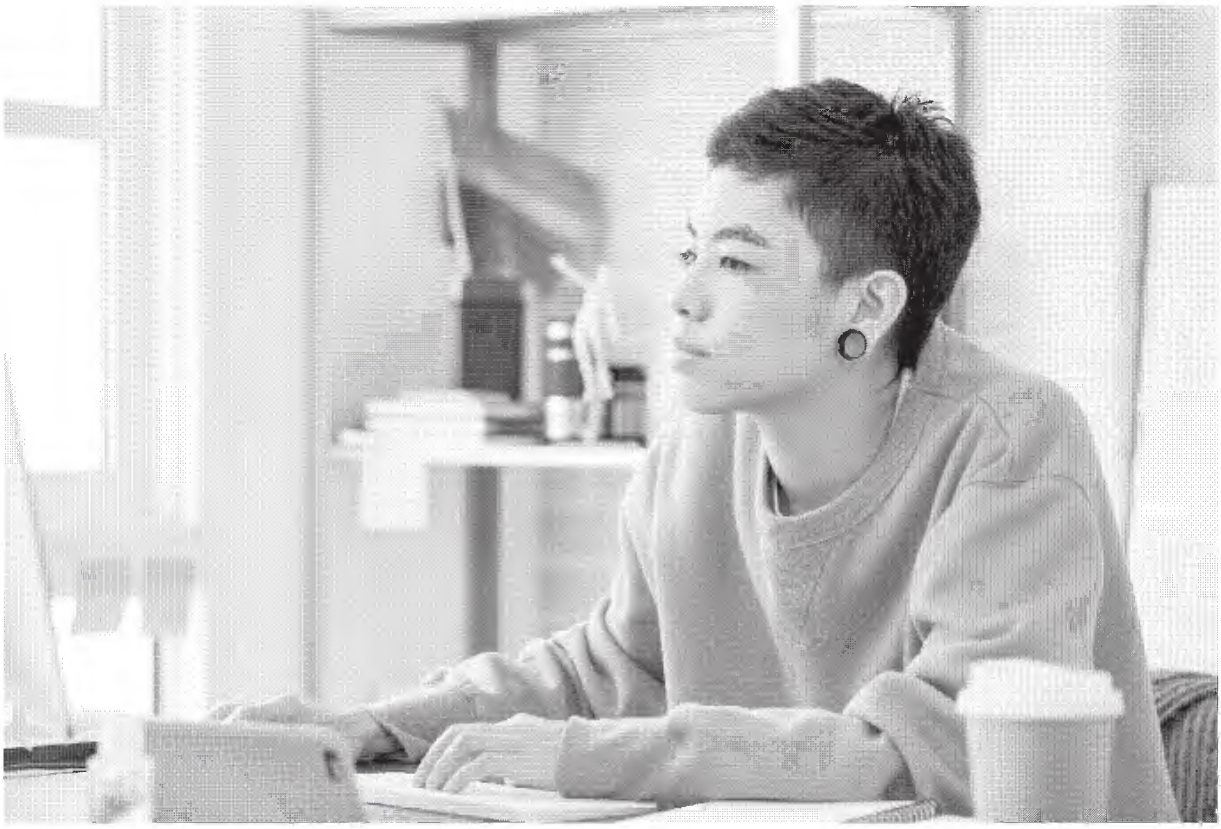
Interventions to Support Children and Families

Families play an important protective role in child development and benefit from information

about how to appropriately help their children. The Family Acceptance Project provides such resources through publications for diverse families, which are available in multiple languages.[394] Other resources include Lead with Love, PATHS and AFFIRM Caregiver (see Appendix C), and information offered by SAMHSA[395] and the Centers for Disease Control and Prevention.[396] The American Psychological Association provides a guide for parents in choosing an appropriate therapist with gender expertise.[397]

Education for families, caregivers, child welfare professionals, and individuals can be tailored to the specific needs of diverse communities.[397,398,399] One option is a public health campaign to educate parents and caregivers on appropriate treatment options that are safe and effective for youth. Such a program can alert families, caregivers, child welfare professionals, schools, and communities on the risks of family rejection and SOGI change efforts and the benefits of recognizing sexual orientation and gender development and access to affirming care.

Healthcare providers can offer age-specific guidance to parents and guardians to help them understand growth- and development-related expectations associated with healthy behaviors and disease prevention; this is known as anticipatory guidance.[400] Pediatricians and behavioral health providers have urged for more anticipatory guidance[401] that pediatricians and early childhood and educational providers can provide to inform parents about sexual orientation and gender identity, as well as their LGBTQI+ child's needs. This would aim to enhance family support and reduce rejection.[402]



The American Academy of Pediatrics urges pediatricians to assess risk factors related to child maltreatment in their general assessments of children and adolescents.[403]Seeking gender-affirming assessment, consultation, and care is not maltreatment.[352,353] The Information Memorandum issued March 2, 2022, by HHS makes clear that state child welfare systems should support LGBTQI+ youth and ensure their safety.[354]

Interventions to Support Youth in Schools

Education and behavioral health associations, professionals, and researchers across the country have urged proactive steps to support and protect LGBTQI+ youth and other students through the inclusion of policies, resources, and training that provide information, safety, and support.[356,361,404,405] These policies have been evaluated over the past decade in nationwide samples and are found to reduce victimization and behavioral health problems and improve mental health.[198,287,288,406,407]

The Society for Research in Child Development,[356] the American Psychological Association,[361] the American Counseling Association,[406] the National Association of School Psychologists, and medical professionals recommend crucial educational policies to create a positive and healthy environment for all youth, especially those who are LGBTQI+ or have emerging sexual orientation or gender identities. These include the following:

1. Establish and implement supportive policies that provide guidelines for respectful interactions (in-person and online), promote acceptance of all sexual orientations and gender identities and expressions, promote the use of identified pronouns, and respect confidentiality and privacy.
2. Enable full participation and access to school activities including athletics and resources for all students and school personnel consistent with their gender identity, including use of school facilities (e.g., bathrooms, locker rooms) that align with their gender identity.
3. Establish protective policies, such as antibullying and antidiscrimination policies, that explicitly include protections for sexual orientation, gender identity, and gender expression.
4. Provide high-quality, evidence-informed LGBTQI+ professional development for school staff.
5. Develop school resources for LGBTQI+ youth and connect to supportive resources and information, such as GSAs, school clubs that are inclusive of LGBTQI+ people, and age-appropriate curriculum that is inclusive of LGBTQI+ people.

   Title IX prohibits sex-based discrimination in any school or any other education program that receives funding from the Federal Government. HHS and the Department of Education have clarified legal requirements with their interpretation of Title IX prohibiting discrimination on the basis of sexual orientation and gender identity. Strong antidiscrimination policies can protect LGBTQI+ youth and their families from discrimination in federal programs.

The Federal government has created a website with information on bullying prevention, including information on bullying of LGBTQI+ youth, ways to create safe school environments, and applicable federal civil rights laws: stopbullying.gov. Such nondiscrimination efforts to ensure the safety and well-being of LGBTQI+ youth and their families in schools and other federal programs are consistent with existing

behavioral health research and professional association recommendations.[355,356,407]

Some states and localities have established such education policies, but they are far from universal. More states have added protective policies over the past 7 years, but a majority of states do not have policies to protect LGBTQI+ students from bullying or discrimination. Inclusive policies are still rare at the state level. Some states are considering and enacting laws and policies that are inconsistent with the above empirically based recommendations, such as those that prevent discussion of LGBTQI+ issues or exclude LGBTQI+ youth from activities or athletics. Given the strength of the evidence of the benefits of the protective policies, policies that stigmatize youth of diverse sexual orientation and/or gender identity pose risks to their health.[354,355,356]

Future Directions: Research to Improve Care

Scientific research can advance our understanding of LGBTQI+ youth and improve their behavioral health through prevention and new interventions.

Increasing Research Insights Through Inclusive Demographic Questions

Health policy experts have called for data collection and priorities that are inclusive of LGBTQI+ people to ensure research accuracy and health equity.[408,409,410,411] Inclusive data collection and research policies support consistent collection of demographic information, including information about respondent sexual orientation and gender identity, regardless of whether the survey is focused on LGBTQI+ populations. Having accurate data and information about sexual orientation and gender identity improves public policies by identifying specific behavioral health needs, preventing adverse health conditions, and addressing health inequities. This is especially true when addressing the diversity within children, adolescents, and their families based on cultural background, ethnicity, race, geography, and other aspects of identity.

Progress has been made in federal, state, and municipal data collection and research as demographic information on sexual orientation and gender identity has been added to some research tools and health records.[412] In 2023, the Federal Government released the first-ever Federal Evidence Agenda for LGBTQI+ Equity, a roadmap that federal agencies will use to ensure they are collecting the data and evidence they need to improve the lives of LGBTQI+ Americans.[413] Other existing efforts include the Centers for Disease Control and Prevention's Youth Risk Behavior Survey (YRBS), which includes national, state, and local surveys, assesses key behavioral and other health risks in youth and includes questions on sexual orientation and sex of sex partners in the national survey.[414] However, although the state and local surveys are currently conducted in 47 states and 28 large urban school districts, not all states and local jurisdictions include sexual orientation and sex of sex partner questions. Questions on gender identity and self-identification as transgender are available for states and local jurisdictions to include in their YRBS surveys, consistent with the Protection of Pupil Rights Amendment, and utilization of those questions has been increasing during each administration of the survey.

There are resources for addressing this gap in data collection on sexual orientation and gender identity. The National Academies report, *Measuring Sex, Gender Identity, and Sexual Orientation,* commissioned by the National Institutes of Health (NIH), provides recommendations on how to formulate appropriate questions regarding sexual

orientation and gender identity to address the complexity of diversity within these communities.[31] For example, an important recommendation is ensuring that approaches to SOGI measurement and data collection are tested and validated in youth populations. Given the diversity of the LGBTQI+ population, it is important to use an intersectional approach that considers multiple aspects of diversity and demography (e.g., cultural background, values, ethnicity, geography, and race).

Selected LGBTQI+ Research Topics

Studies of LGBTQI+ youth have begun to examine important developmental and clinical needs in these populations. Focused research can expand our understanding of these youth and guide clinical interventions. For example, studies of development of transgender children provide new windows into our understanding of gender development and well-being in childhood.[189] Research to elucidate how intersecting sociocultural factors and experiences (e.g., race, ethnicity, socioeconomic status, cultural background and values) influence sexual orientation and gender development is in its early stages. To better understand the needs of sexual and gender minority children and adolescents, new lines of research can include sexual- and gender-diverse children and adolescents from diverse family backgrounds, especially from general populations rather than those limited to samples of people receiving clinical care.

Intersex individuals face known health disparities although research that specifically focuses on intersex individuals is limited and needs to be expanded both broadly and across time within longitudinal studies.[45,415] The Administration's Federal Evidence Agenda on LGBTQI+ Equity identified a lack of national surveys that collect data about "variations in sex characteristics or intersex people" and underscored the need to collect those data.[413]

Limited research has considered economic impact of SOGI change efforts, which could be expanded. A recent study found negative economic consequences for those adolescents and young adults who experience SOGI change efforts when compared to those with no intervention or affirming interventions. These negative economic impacts include the costs associated with adverse events as well as the expense of the efforts.[416] Further, despite its lack of efficacy and its serious harms to clients, SOGI change efforts appear to be lucrative, which may serve as an inducement to some providers.[416]

Evaluations of clinical approaches and development of best practices can be fostered by funding research collaborations; this type of research can lead to improved care.[214,417] Key research areas should also include suicide prevention, evidence-based trauma-focused interventions, and approaches to counter minority stress. Studies of community-based populations provide an emerging understanding of the key developmental concerns. A resource for those conducting LGBTQI+ research is the NIH Sexual and Gender Minority Research Office. NIH has also developed tools to study social determinants of health.[418] A National Academies report includes recommendations on key areas of LGBTQI+ research.[31]

Summary and Conclusions

SAMHSA is committed to eliminating health inequities experienced by marginalized communities, including LGBTQI+ youth. To build a healthy and supportive environment for all youth, families, caregivers, providers, and educators need resources and accurate information to inform healthy decision making. Two key strategies that can help prevent adverse outcomes and support healthy development for LGBTQI+ youth are:

1. Strong and positive family, school, and community engagement
2. Appropriate and supportive therapeutic interventions by physical and behavioral health providers

Policies at the local, state, and federal levels are needed to foster supportive, affirming environments and ensure access to appropriate care.

These strategies must and can be grounded in research. Being a sexual or gender minority, or identifying as LGBTQI+, is not a mental disorder. Variations in sexual orientation, gender identity, and gender expression are normal and healthy. Sexual- and gender-diverse youth have unique health and behavioral health needs and may experience distress due to discrimination and barriers to support that remain widespread for LGBTQI+ youth. In addition, transgender and gender-diverse youth may experience distress caused by the incongruence between their gender identity and physical body.

Current research, evolving clinical expertise, and expert consensus underscore that efforts to attempt to change a youth's sexual orientation, gender identity, or gender expression are never appropriate. No evidence supports the efficacy of such interventions, and evidence shows that they can cause severe harm. Appropriate therapeutic approaches to working with LGBTQI+ youth include:

- Providing accurate information on sexual orientation and gender identity and expression
- Identifying sources of and working to reduce distress
- Supporting adaptive coping
- Supporting youth as they learn more about their sexual orientation and gender identity, and supporting families in accessing gender-affirming care for their transgender child when indicated
- Helping youth navigate sexual orientation, gender identity and expression within the context of other intersecting identities

Additionally, providers can help increase family and school support, and reduce family, community, and social rejection of LGBTQI+ youth. Social transition and medical interventions, including pubertal suppression and hormone therapy, are additional therapeutic approaches that may be medically necessary, appropriate, and beneficial for gender minority youth based on the individual youth's needs. Withholding timely gender-affirming medical care when indicated, withholding support for a gender-affirming exploratory process, and/or withholding support of social transition when desired, can be harmful. These actions may exacerbate gender dysphoria.

Beyond ending harmful change efforts, it is important to build greater social acceptance of LGBTQI+ youth across all environments where they live, learn, and play; adopt appropriate and

supportive interventions; and provide targeted resources and accurate developmentally informed information for children, adolescents, their families, and providers. Building better supportive environments and working to eliminate negative social attitudes will reduce health inequities and improve the health and well-being of LGBTQI+ youth.

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Appendix B: Glossary of Terms

Agender: Describes individuals who do not identify as any gender.

Asexual: Describes individuals who do not experience sexual attraction. An individual can also be aromantic, meaning that they do not experience romantic attraction.

Behavioral health: A broad term that includes mental health, resilience, and well-being; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

Behavioral health provider: A broad term used here to describe individuals across settings and disciplines who are engaged in the provision of care and/or support related to behavioral health. Behavioral health providers include both licensed and non-licensed professionals, including mental health counselors, marriage and family therapists, pastoral counselors, psychiatrists, psychologists, psychiatric nurses, school counselors and health providers, peer support professionals, social workers, substance use counselors, addiction medicine specialists, and all staff of mental health and substance use treatment facilities.

Bisexual: Describes an individual who has the capacity to form enduring physical, romantic, and/or emotional attractions to those of the same gender or to those of another gender.

Cisgender: Describes individuals whose gender identity is congruent with their sex assigned at birth.

Developmentally sensitive approaches: Clinical and educational approaches that account for the appropriate developing emotional and cognitive capacities, developmental milestones, and emerging or existing behavioral health concerns.

Diverse sexual orientation and/or gender identity: A term to describe persons who are lesbian, gay, bisexual, transgender, queer, intersex, those who are questioning their sexual orientation or gender identity, and others who are not cisgender or straight/heterosexual. Diverse sexual orientation and/or gender identity is used interchangeably with "LGBTQI+" and "sexual and/or gender minority" (or similar language) throughout this report.

Fa'afafine: Describes individuals assigned male sex at birth who identify themselves as having a third gender or nonbinary in Samoan culture.

Gay: Describes individuals whose enduring physical, romantic, and/or emotional attractions are to people of the same gender.

Gender-affirming care: A specialized model of care used in the treatment of gender dysphoria that uses evidence-informed treatment options to promote patient health and prevent the risk of poor mental and physical health outcomes. Not all youth need to undergo medical intervention; indeed, this is often not the case. Gender-affirming care is highly individualized and focuses on the needs of each individual. Gender-affirming care may include psychoeducation about gender and sexuality (appropriate to the age and developmental level), parental and family support, social interventions, and gender-affirming medical interventions.

Gender diverse: A broad term that includes individuals whose gender identities and/or gender expressions are incongruent with those culturally expected based on sex assigned at birth. This includes those who are exploring their gender and is used interchangeably with "gender minority."

Gender expression: The external ways a person communicates their gender, such as clothing, hair, mannerisms, activities, or social roles.

Gender fluid: A term used to describe individuals whose gender changes over time.

Gender identity: A person's deep internal sense of being female, male, or another identity.

Genderqueer: Describes individuals who experience their gender identity and/or gender expression as falling outside the categories of man and woman.

Intersex: An umbrella term used to describe people with variations in sex characteristics, including chromosomes or hormones that do not fit typical definitions of male and female.

Lesbian: A woman who has romantic and/or sexual orientation toward women.

LGBTQI+: Lesbian, gay, bisexual, transgender, queer, intersex, those who are questioning their sexual orientation or gender identity, and others who are not cisgender or straight/heterosexual. LGBTQI+ is used interchangeably with "sexual and/or gender minority" and persons of "diverse sexual orientation and/or gender identity" (or similar language) throughout this report.

Māhū: Describes individuals who identify as a third gender or nonbinary in Native Hawaiian culture.

Nonbinary: Describes individuals whose gender identity is not exclusively male or female. Individuals may identify as nonbinary or other identities, including, but not limited to, genderqueer, two-spirit, agender, bigender, and genderfluid.

Pansexual: Describes individuals who experience sexual, romantic, physical, and/or spiritual attraction for members of all gender identities/expressions.

Queer: Historically, this has been a pejorative term used to describe LGBTQI+ people, but is now used by some people, particularly younger people, whose sexual orientation is not exclusively straight/heterosexual. Some people may use queer, or more commonly genderqueer, to describe their gender identity and/or gender expression.

Questioning: A term used to describe individuals who are unsure about their sexual orientation and/or gender identity.

Sex assigned at birth: The assignment of male, female, or intersex when an individual is born, typically made based on the appearance of external genital anatomy.

Sexual and/or gender minority: Sexual and gender minority populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. Sexual and gender minority is used interchangeably with "LGBTQI+" and persons of "diverse sexual orientation and/or gender identity" (or similar) throughout this report.

Sexual orientation and gender identity change efforts (SOGI change efforts): Practices that aim to suppress or alter an individual's sexual orientation or gender to align with heterosexual orientation, cisgender identity, and/or stereotypical gender expression. Though not therapeutic, these practices are often referred to as "conversion therapy" or "reparative therapy."

Sexual orientation: A person's emotional, sexual, and/or relational attraction to others.

Transgender: Describes individuals whose gender identity is incongruent with their sex assigned at birth.

Two-Spirit: Two Spirit refers to someone who is Native and expresses their gender identity or spiritual identity in indigenous, non-Western ways. This term can only be applied to a person who is Native. A Two Spirit person has specific traditional roles and responsibilities within their tribe. Not all Native LGBTQ people identify as Two Spirit.

Victimization: The act or process of singling someone out for cruel or unfair treatment, typically through physical or emotional abuse.

This glossary is not an exhaustive list of terminology relevant for LGBTQI+ youth. Additional key terms and concepts are defined at Youth.gov.

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Appendix C: Selected Resources

This appendix highlights selected materials that are accessible to a variety of providers, community professionals, parents, caregivers, and youth. It also includes resources that, after reviewing, professionals may share with families, youth, and community-based collaborators. The appendix does not cover every important aspect of all issues addressed in this report, and the list of resources is illustrative, not exhaustive.

The Department of Health and Human Services maintains information online at: https://www.hhs.gov/programs/topic-sites/lgbtq/index.html

If you or someone you know is in crisis or emotional distress, or experiencing suicidal thoughts, please contact:

988 Suicide and Crisis Lifeline

If you're thinking about suicide, are worried about a friend or loved one, or would like emotional support, the Lifeline network is available 24/7.

- **Dial: 988**
- **Text: 988**
- **Chat: https://988Lifeline.org/chat**

The Trevor Project

***Connect to a crisis counselor*:**
866-488-7386 |
www.thetrevorproject.org/get-help

LGBT National Help Center

Peer support: www.lgbthotline.org

Resources for Behavioral Health and Medical Providers

Resources for Understanding Sexual Orientation and Gender Identity

These resources include information on sexual orientation and gender identity and development for behavioral health providers and other professionals.

Online Resources for Providers

- American Counseling Association. (n.d.). https://www.counseling.org/knowledge-center/mental-health-resources/lgbtq
- American Psychological Association. (n.d.). https://www.apa.org/topics/lgbtq
- National LGBTQIA+ Health Education Center. (n.d.). https://www.lgbtqiahealtheducation.org/resources/in/transgender-health/
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- World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People. https://www.wpath.org/publications/soc
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- National Child Traumatic Stress Network. (2022). Gender-Affirming Care Is Trauma-Informed Care. https://www.nctsn.org/sites/default/files/resources/fact-sheet/gender-affirming-care-is-trauma-informed-care.pdf

Books for Providers

- Irwin Krieger. (2018). *Counseling Transgender and Non-Binary Youth: The Essential Guide*. London: Jessica Kingsley Publishers, Ltd.
- Colt Keo-Meier and Diane Ehrensaft. (2018). *The Gender Affirmative Model: An Interdisciplinary Approach to Supporting Transgender and Gender Expansive Children*. Washington, DC: American Psychological Association.

Resources for Pediatric and Primary Care Providers

In addition to the resources above, these selected resources assist pediatric and primary care health professionals who may be the first point of contact for families and youth.

- Rafferty J; Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4):e20182162. doi:10.1542/peds.2018-2162. https://pubmed.ncbi.nlm.nih.gov/30224363/
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- National LGBT Health Education Center. (n.d.). https://www.lgbtqiahealtheducation.org/resources/in/transgender-health/

Resources for Providers to Discuss with Families, Caregivers, and Others

These resources are designed for professionals to discuss with families, caregivers, and others.

- HHS. (n.d.). LGBTQI+ Health & Well-being. https://www.hhs.gov/programs/topic-sites/lgbtqi/index.html
- The Family Acceptance Project http://familyproject.sfsu.edu/ works with parents and caregivers to help them support their LGBTQI+ youth to reduce health risks and promote well-being. This information is offered within the context of diverse cultures and faith communities by identifying and understanding the impacts of rejecting and supportive behaviors. Films, posters and trainings are available for behavioral health providers and others and information is provided for families in many languages. http://familyproject.sfsu.edu/
- OASH. Office of Population Affairs. (2022). *Gender-Affirming Care and Young People*. https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf
- AFFIRM Caregiver is a seven-session intervention that helps caregivers clarify what supportive behaviors are and how to move away from rejecting behaviors. https://www.affirmativeresearch.org/affirm-care.html

Resources for Providers on Cultural Responsiveness

These resources highlight the scientific consensus for assisting professionals who work with diverse families and youth.

- Asian American Psychological Association. (n.d.). https://aapaonline.org/resources/lgbtq-aapi-resources/
- 2019 Black and African American LGBTQ Youth Report. (2019). https://www.hrc.org/resources/black-and-african-american-lgbtq-youth-report
- The Trevor Project. (July 14, 2021). Black & LGBTQ: Approaching Intersectional Conversations. https://www.thetrevorproject.org/resources/guide/black-lgbtq-approaching-intersectional-conversations/
- The Trevor Project. (June 1, 2020). Supporting Black LGBTQ Mental Health. https://www.thetrevorproject.org/resources/guide/supporting-black-lgbtq-youth-mental-health/
- 2018 LGBTQ Latinx Youth Report. (2018). https://www.hrc.org/resources/latinx-lgbtq-youth-report
- National Queer Asian Pacific Islander Alliance (NQAPIA). (n.d.). http://www.nqapia.org

Resources for Educators and School and Community Leaders

Resources for School Professionals

These resources highlight approaches that build educator support and student resilience.

- Advocates for Youth. (2020). *Creating Safer Spaces for LGBTQ Youth: A Toolkit for Education, Healthcare and Community-Based Organizations.* http://www.advocatesforyouth.org/wp-content/uploads/2020/11/Creating-Safer-Spaces-Toolkit-Nov-13.pdf
- American Psychological Association. (2014). Safe & Supportive Schools Project. http://www.apa.org/pi/lgbt/programs/safe-supportive/default.aspx
- GLSEN Research Institute. (2021). *LGBTQ Students and School Sports Participation: Research Brief.* https://www.glsen.org/sites/default/files/2022-02/LGBTQ-Students-and-School-Sports-Participation-Research-Brief.pdf
- Additional GLSEN Resources. (n.d.). https://www.glsen.org/
- CDC DASH Supporting LGBTQ Youth. (n.d.). https://www.cdc.gov/healthyyouth/safe-supportive-environments/lgbtq_youth.htm
- Human Rights Campaign, Welcoming Schools Initiative. (n.d.). Creating Safe and Welcoming Schools. www.welcomingschools.org
- National Center for Lesbian Rights, Youth Project. (n.d.). www.nclrights.org/our-work/youth
- National Association of School Psychologists, Committee on LGBTQI2-S Issues: Safe & Supportive Schools. (n.d.). https://www.nasponline.org/lgbtqi2-s

Resources for Families and Caregivers

Parent/Caregiver Support-Focused Resources

These resources highlight ways for parents and caregivers to connect with other parents and caregivers of LGBTQI+ youth, and to learn more about their responses to LGBTQI+ youth.

- PFLAG. (n.d.) Families connecting with other families. www.pflag.org

- National Queer Asian Pacific Islander Alliance (NQAPIA). (n.d.). Videos and resources for parents. https://www.youtube.com/user/nqapia/videos
- Lead with Love (n.d.). Film-based intervention to improve parental responses to their sexual minority children. www.leadwithlovefilm.com

Resources for Families and Caregivers of Transgender and Gender-Diverse Youth

These resources highlight specific considerations for parents and caregivers of gender minority youth.

Online Resources for Families and Caregivers

- American Psychological Association. (December 2020). *A Consumer's Guide for Parents and Guardians of Gender Diverse Children and Adolescents: 10 Considerations for Finding a Gender Competent Therapist for Your Child*. https://www.apa.org/pi/lgbt/resources/gender-diverse-children.pdf
- PFLAG Transgender Network. (n.d.). https://pflag.org/transgender
- Gender Spectrum offers resources for multiple audiences. (n.d.). www.genderspectrum.org

Books for Families and Caregivers

- Janna Barkin. (2017). *He's Always Been My Son: A Mother's Story About Raising her Transgender Son*. London: Jessica Kingsley Publishers, Ltd.
- Stephanie Brill and Lisa Kenney. (2016). *The Transgender Teen: A Handbook for Parents and Professionals Supporting Transgender and Non-Binary Teens*. Jersey City, NJ: Cleis Press.
- Diane Ehrensaft. (2011). *Gender Born, Gender Made: Raising Healthy Gender-Nonconforming Children* (1st ed.). New York: The Experiment.
- Irwin Krieger. (2019). *Helping Your Transgender Teen* (2nd ed.). New Haven, CT: Genderwise Press.
- Jodie Patterson. (2019). *The Bold World: A Memoir of Family and Transformation*. New York: Penguin Random House.
- Rachel Pepper. (2012). *Transitions of the Heart: Stories of Love, Struggle and Acceptance by Mothers of Transgender and Gender Variant Children*. Jersey City, NJ: Cleis Press.

Resources for Youth

Online Resources for Youth

These resources are places where LGBTQI+ youth can access information and online support.

- It Gets Better Project. (n.d.). www.itgetsbetter.org
- The Trevor Project. (n.d.). www.thetrevorproject.org
- Gender Spectrum. www.genderspectrum.org

Appendix D: Contributions

This report was prepared for SAMHSA by Leed Management Consulting, Inc. (LMCi) under contract number HHSS283201700609I/HHSS28342001T with SAMHSA, U.S. Department of Health and Human Services (HHS). Arlin Hatch, CAPT, USPHS, PhD, served as the Task Lead, Aida Balsano, PhD, served as the Deputy Task Lead, and Brian Altman, JD, served as Senior Advisor. David Lamont Wilson, BFA, served as the Contracting Officer Representative, and Marion Pierce, BA, served as the Alternate Contracting Officer Representative.

Laura Jadwin-Cakmak, MPH, was the lead scientific writer for this report, with substantial contributions from Judith Glassgold, PsyD; assistance from the subject matter expert panelists; technical, bibliographic, and editorial assistance from Kathi E. Hanna, PhD; and support from Karen Braxton, MA, as task lead from LMCi.

The Subject Matter Expert Consensus Panel was convened by Judith Glassgold, PsyD, the lead subject matter expert, remotely from September 9 to 10, 2021, with technical support from LMCi. The Panel included researchers and practitioners in child and adolescent development and mental health, as well as researchers in gender development, gender identity, and sexual orientation in children and adolescents. The Panel also included experts with a background in family therapy, ethnic and racial diversity, the needs of underrepresented populations, the intersection of behavioral health and spiritual diversity, and ethics. Panel members were Renata Arrington-Sanders, MD, MPH, ScM; Laura Edwards-Leeper, PhD; Gary Harper, PhD, MPH; Laura Kuper, PhD; Scott Leibowitz, MD; Christy Mallory, JD; Robin Lin Miller, PhD; Kristina Olson, PhD; Thomas Plante, PhD; Clifford Rosky, JD; Caitlin Ryan, PhD, ACSW; Russell Toomey, PhD; and Mark Yarhouse, PsyD.

SAMHSA subject matter experts provided input on the report: Brian Altman, JD; Amy Andre, MA, MBA; Mitchell Berger, MPH; Victoria Chau, PhD, MPH; Jeff Coady, CAPT, USPHS, PsyD, ABPP; Ed Craft, DrPh, Med, LCPC; Trina Dutta, MPP, MPH; and Michelle Kim Leff, CAPT, USPHS, MD, MBA. Elliot Kennedy, JD, from the Administration for Community Living, provided consultation and served as the SAMHSA Task Lead for the 2015 report, *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth*, on which this revision is based.

SAMHSA
Substance Abuse and Mental Health Services Administration

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Any person depicted in a photo is a model.

Publication No. No. PEP22-03-12-001
Released 2023

TAB 176-36

Presidential Documents

Pl. Trial Ex. 076

Proclamation 10355 of March 30, 2022

Transgender Day of Visibility, 2022

By the President of the United States of America

A Proclamation

To everyone celebrating Transgender Day of Visibility, I want you to know that your President sees you. The First Lady, the Vice President, the Second Gentleman, and my entire Administration see you for who you are—made in the image of God and deserving of dignity, respect, and support. On this day and every day, we recognize the resilience, strength, and joy of transgender, nonbinary, and gender nonconforming people. We celebrate the activism and determination that have fueled the fight for transgender equality. We acknowledge the adversity and discrimination that the transgender community continues to face across our Nation and around the world.

Visibility matters, and so many transgender, nonbinary, and gender nonconforming Americans are thriving. Like never before, they are sharing their stories in books and magazines; breaking glass ceilings of representation on television and movie screens; enlisting—once again—to serve proudly and openly in our military; getting elected and making policy at every level of government; and running businesses, curing diseases, and serving our communities in countless other ways.

Despite this progress, transgender Americans continue to face discrimination, harassment, and barriers to opportunity. Transgender women and girls—especially transgender women and girls of color—continue to face epidemic levels of violence, and 2021 marked the deadliest year on record for transgender Americans. Each of these lives lost was precious. Each of them deserved freedom, justice, and joy. We must honor their lives with action by advancing equity and civil rights for all transgender people.

In the past year, hundreds of anti-transgender bills in States were proposed across America, most of them targeting transgender kids. The onslaught has continued this year. These bills are wrong. Efforts to criminalize supportive medical care for transgender kids, to ban transgender children from playing sports, and to outlaw discussing LGBTQI+ people in schools undermine their humanity and corrode our Nation's values. Studies have shown that these political attacks are damaging to the mental health and well-being of transgender youth, putting children and their families at greater risk of bullying and discrimination.

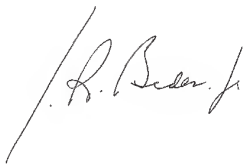
My entire Administration is committed to ensuring that transgender people enjoy the freedom and equality that are promised to everyone in America. That is why I signed an Executive Order Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. We are expanding Federal non-discrimination protections; promoting strategies to address violence against the transgender community and advance gender equity and equality; and disseminating new resources to enhance inclusion, opportunity, and safety for transgender people. Additionally, Americans will soon be able to select more inclusive gender markers on their passports. I continue to call on the Congress to swiftly pass the bipartisan Equality Act, which will ensure that LGBTQI+ individuals and families cannot be denied housing, employment, education, credit, and more because of who they are or who

they love. We will continue to work to help transgender people around the world live free from discrimination and violence.

On this Transgender Day of Visibility, we honor transgender people who are fighting for freedom, equality, dignity, and respect. We also celebrate the parents, teachers, coaches, doctors, and other allies who affirm the identities of their transgender children and help these young people reach their potential. Transgender people are some of the bravest Americans I know, and our Nation and the world are stronger, more vibrant, and more prosperous because of them. To transgender Americans of all ages, I want you to know that you are so brave. You belong. I have your back.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 31, 2022, as Transgender Day of Visibility. I call upon all Americans to join us in lifting up the lives and voices of transgender people throughout our Nation and to work toward eliminating discrimination against all transgender, gender nonconforming, and nonbinary people—and all people.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of March, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-sixth.



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TAB 176-37

Presidential Documents

Pl. Trial Ex. 077

Proclamation 10538 of March 30, 2023

Transgender Day of Visibility, 2023

By the President of the United States of America

A Proclamation

Transgender Day of Visibility celebrates the joy, strength, and absolute courage of some of the bravest people I know—people who have too often had to put their jobs, relationships, and lives on the line just to be their true selves. Today, we show millions of transgender and nonbinary Americans that we see them, they belong, and they should be treated with dignity and respect. Their courage has given countless others strength, but no one should have to be brave just to be themselves. Every American deserves that freedom.

Transgender Americans shape our Nation's soul—proudly serving in the military, curing deadly diseases, holding elected office, running thriving businesses, fighting for justice, raising families, and much more. As kids, they deserve what every child deserves: the chance to learn in safe and supportive schools, to develop meaningful friendships, and to live openly and honestly. As adults, they deserve the same rights enjoyed by every American, including equal access to health care, housing, and jobs and the chance to age with grace as senior citizens. But today, too many transgender Americans are still denied those rights and freedoms. A wave of discriminatory State laws is targeting transgender youth, terrifying families and hurting kids who are not hurting anyone. An epidemic of violence against transgender women and girls, in particular women and girls of color, has taken lives far too soon. Last year's Club Q shooting in Colorado was another painful example of this kind of violence—a stain on the conscience of our Nation.

My Administration has fought to end these injustices from day one, working to ensure that transgender people and the entire LGBTQI+ community can live openly and safely. On my first day as President, I issued an Executive Order directing the Federal Government to root out discrimination against LGBTQI+ people and their families. We have appointed a record number of openly LGBTQI+ leaders, and I was proud to rescind the ban on openly transgender people serving in the military. We are also working to make public spaces and travel more accessible, including with more inclusive gender markers on United States passports. We are improving access to public services and entitlements like Social Security. We are cracking down on discrimination in housing and education. And last December, I signed the Respect for Marriage Act into law, ensuring that every American can marry the person they love and have that marriage accepted, period.

Meanwhile, we are also working to ease the tremendous strain that discrimination, bullying, and harassment can put on transgender children—more than half of whom seriously considered suicide in the last year. The Department of Education is, for example, helping ensure that transgender students have equal opportunities to learn and thrive at school, and the Department of Justice is pushing back against extreme laws that seek to ban evidence-based gender-affirming health care.

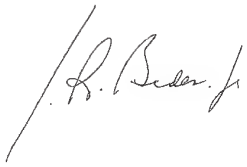
There is much more to do. I continue to call on the Congress to finally pass the Equality Act and extend long-overdue civil rights protections to all LGBTQI+ Americans to ensure they can live with safety and dignity.

Together, we also have to keep challenging the hundreds of hateful State laws that have been introduced across the country, making sure every child knows that they are made in the image of God, that they are loved, and that we are standing up for them.

America is founded on the idea that all people are created equal and deserve to be treated equally throughout their lives. We have never fully lived up to that, but we have never walked away from it either. Today, as we celebrate transgender people, we also celebrate every American's fundamental right to be themselves, bringing us closer to realizing America's full promise.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 31, 2023, as Transgender Day of Visibility. I call upon all Americans to join us in lifting up the lives and voices of transgender people throughout our Nation and to work toward eliminating violence and discrimination against all transgender, gender nonconforming, and nonbinary people.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of March, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Presidential Documents

Pl. Trial Ex. 078

Executive Order 13988 of January 20, 2021

Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy*. Every person should be treated with respect and dignity and should be able to live without fear, no matter who they are or whom they love. Children should be able to learn without worrying about whether they will be denied access to the restroom, the locker room, or school sports. Adults should be able to earn a living and pursue a vocation knowing that they will not be fired, demoted, or mistreated because of whom they go home to or because how they dress does not conform to sex-based stereotypes. People should be able to access healthcare and secure a roof over their heads without being subjected to sex discrimination. All persons should receive equal treatment under the law, no matter their gender identity or sexual orientation.

These principles are reflected in the Constitution, which promises equal protection of the laws. These principles are also enshrined in our Nation's anti-discrimination laws, among them Title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e *et seq.*). In *Bostock* v. *Clayton County*, 590 U.S.__(2020), the Supreme Court held that Title VII's prohibition on discrimination "because of . . . sex" covers discrimination on the basis of gender identity and sexual orientation. Under *Bostock's* reasoning, laws that prohibit sex discrimination—including Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681 *et seq.*), the Fair Housing Act, as amended (42 U.S.C. 3601 *et seq.*), and section 412 of the Immigration and Nationality Act, as amended (8 U.S.C. 1522), along with their respective implementing regulations—prohibit discrimination on the basis of gender identity or sexual orientation, so long as the laws do not contain sufficient indications to the contrary.

Discrimination on the basis of gender identity or sexual orientation manifests differently for different individuals, and it often overlaps with other forms of prohibited discrimination, including discrimination on the basis of race or disability. For example, transgender Black Americans face unconscionably high levels of workplace discrimination, homelessness, and violence, including fatal violence.

It is the policy of my Administration to prevent and combat discrimination on the basis of gender identity or sexual orientation, and to fully enforce Title VII and other laws that prohibit discrimination on the basis of gender identity or sexual orientation. It is also the policy of my Administration to address overlapping forms of discrimination.

Sec. 2. *Enforcing Prohibitions on Sex Discrimination on the Basis of Gender Identity or Sexual Orientation*. (a) The head of each agency shall, as soon as practicable and in consultation with the Attorney General, as appropriate, review all existing orders, regulations, guidance documents, policies, programs, or other agency actions ("agency actions") that:

(i) were promulgated or are administered by the agency under Title VII or any other statute or regulation that prohibits sex discrimination, including any that relate to the agency's own compliance with such statutes or regulations; and

(ii) are or may be inconsistent with the policy set forth in section 1 of this order.

(b) The head of each agency shall, as soon as practicable and as appropriate and consistent with applicable law, including the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), consider whether to revise, suspend, or rescind such agency actions, or promulgate new agency actions, as necessary to fully implement statutes that prohibit sex discrimination and the policy set forth in section 1 of this order.

(c) The head of each agency shall, as soon as practicable, also consider whether there are additional actions that the agency should take to ensure that it is fully implementing the policy set forth in section 1 of this order. If an agency takes an action described in this subsection or subsection (b) of this section, it shall seek to ensure that it is accounting for, and taking appropriate steps to combat, overlapping forms of discrimination, such as discrimination on the basis of race or disability.

(d) Within 100 days of the date of this order, the head of each agency shall develop, in consultation with the Attorney General, as appropriate, a plan to carry out actions that the agency has identified pursuant to subsections (b) and (c) of this section, as appropriate and consistent with applicable law.

Sec. 3. *Definition.* "Agency" means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).

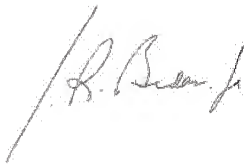
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 20, 2021.

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