Exhibit 7

1 **UNITED STATES DISTRICT COURT**

2 **DISTRICT OF IDAHO**

3

4 ADREE EDMO (a/k/a MASON EDMO),) CASE NO. 1:17-cv-00151-BLW
)
5 Plaintiff,) **EVIDENTIARY HEARING DAY 1**
)
6 vs.)
)
7 IDAHO DEPARTMENT OF)
CORRECTION; HENRY ATENCIO, in)
8 his official capacity; JEFF)
ZMUDA, in his official)
9 capacity; HOWARD KEITH YORDY,)
in his official and individual)
10 capacities; CORIZON, INC.;)
SCOTT ELIASON; MURRAY YOUNG;)
11 RICHARD CRAIG; RONA SIEGERT;)
CATHERINE WHINNERY; and DOES)
12 1-15,)
)
13 Defendants.)
______________________________)

14

15

16 **TRANSCRIPT OF PROCEEDINGS - VOLUME 1**
BEFORE THE HONORABLE B. LYNN WINMILL
17 **WEDNESDAY, OCTOBER 10, 2018, 8:53 A.M.**
BOISE, IDAHO

18

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20

21

Proceedings recorded by mechanical stenography, transcript
22 produced by computer.
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23

24 **TAMARA I. HOHENLEITNER, CSR 619, CRR**
FEDERAL OFFICIAL COURT REPORTER
25 550 WEST FORT STREET, BOISE, IDAHO 83724

1 dysphoria; I need the surgery. And it's a difference of medical
2 opinion and professional opinion as to whether or not that's
3 appropriate.
4 And until these are well controlled, until her depression
5 is under control, until her anxiety, her sexual concerns, her
6 self-harm issues, and these personality traits can be managed,
7 it would not be appropriate or safe to provide this surgery.
8 A lot of this is speculative. We don't have a lot of data.
9 And that's not why there would be any denial of that, but mental
10 health professionals need the discretion to be able to consider
11 the whole person and to consider whether or not she is mentally
12 stable at this time or was in 2016 when an evaluation for
13 surgery was performed.
14 Your Honor, unless there are any questions, I have nothing
15 further.
16 THE COURT: No. Thank you.
17 All right. Plaintiffs may call their first witness.
18 MS. RIFKIN: Thank you, Your Honor.
19 We would like to call Dr. Randi Ettner.
20 THE COURT: Dr. Ettner, if you would step before the
21 clerk and be sworn.
22 RANDI ETTNER, PH.D., PLAINTIFF'S WITNESS, SWORN
23 THE CLERK: Please take a seat in the witness stand.
24 Please state your complete name and spell your name for the
25 record.

1 A. It was produced in 2011 and widely circulated by 2012.
2 Q. And you also chair the WPATH Committee for
3 Institutionalization Persons; is that right?
4 A. Yes.
5 Q. What does this committee do?
6 A. This committee actually looks at the care and the
7 assessment of individuals who are incarcerated and develops
8 standards for treatment for the standards of care for future
9 iterations and for the past iterations.
10 It looks at case law and different policies, how different
11 federal and state prisons handle the treatment, the placement,
12 and other policies regarding institutionalized people -- not
13 just in prisons but in other long-care facilities where people
14 really don't have agency to access care on their own.
15 Q. How long have you been a member of WPATH?
16 A. Since 1993.
17 Q. And what is your experience treating patients with gender
18 dysphoria?
19 A. I have personally treated 3,000 individuals with gender
20 dysphoria.
21 Q. Have you, as part of that treatment, evaluated whether
22 gender confirmation surgery is necessary for patients?
23 A. Yes. For certain patients, it's medically indicated.
24 Q. And have you referred any patients for gender confirmation
25 surgery?

1 A. I have referred approximately 300 patients for surgery.
2 Q. Do you have any experience interacting with or treating
3 patients after they have undergone gender confirmation surgery?
4 A. Extensive experience. Many of the patients that I have
5 treated will come back years after surgery not about gender
6 dysphoria, because that's been eliminated, but to discuss the
7 kinds of issues that other people have -- problems at work or
8 concerns with their children or other issues.
9 Q. And what is your experience assessing incarcerated patients
10 with gender dysphoria?
11 A. I have assessed approximately 30 individuals in 30
12 different prisons, federal and state, not just for surgery
13 necessarily but for care in general, medical care in general.
14 Q. And you've also authored a number of books on the treatment
15 of gender dysphoria and transgender healthcare?
16 A. That's correct.
17 Q. And on your resume, it includes the "Principles of
18 Transgender Medicine and Surgery."
19 How would you describe this publication?
20 A. That's a textbook that I edited for medical and surgical
21 care. It's used in medical schools and for surgeons. It was
22 revised in 2017.
23 Q. And you have also authored a number of peer-reviewed
24 articles on treatment of gender dysphoria and transgender
25 healthcare?

1 You mentioned earlier this part of the DSM-5 entry for
2 gender dysphoria.
3 Can you explain what "clinically significant distress"
4 means.
5 A. Yes. So clinically significant distress is where the
6 distress reaches a threshold that the person will either require
7 medical or surgical or both interventions, and the distress will
8 impair or severely limit their ability to function in some way.
9 So when you talk about the distinction between transgender
10 and gender dysphoria, for instance, a child who is a tomboy,
11 assigned female at birth, may be displaying some
12 gender-nonconforming behaviors. But that's not the same as
13 gender dysphoria.
14 Q. Is gender dysphoria related to sexual abuse?
15 A. No.
16 Q. Is sexual abuse a contributing factor to gender dysphoria?
17 A. No.
18 Q. And does the condition of gender dysphoria require medical
19 treatment?
20 A. Typically, gender dysphoria does require medical treatment,
21 yes.
22 Q. Why?
23 A. Because it's a medical condition. And like other medical
24 conditions, it can intensify over time, and does.
25 So, for instance, if we compare it to the condition of

1 diabetes, some people may be prediabetic. Perhaps they can
2 control their diabetes with nutrition and exercise; but in time,
3 they may actually require insulin.
4 So the same is true of gender dysphoria. Some people may
5 initially be able to attenuate the gender dysphoria with a
6 social role transition. But if the gender dysphoria is
7 persistent, they will require other treatments, medical and
8 surgical.
9 Q. And what are the risks of not providing treatment to
10 someone with gender dysphoria?
11 A. If the gender dysphoria is severe, the risks are serious.
12 Prison is actually a place where we see the long-term effects of
13 untreated gender dysphoria. We see the natural progression of
14 the condition. And typically the sequelae are either surgical
15 self-treatment where an individual attempts to remove their own
16 genitals, suicide, or severe emotional decompensation.
17 Q. So I would like to talk about the WPATH standards of care
18 that we discussed a little earlier and we have heard some about
19 today.
20 Can we show the witness Joint Exhibit 15.
21 What version of the standards of care are in effect now?
22 A. Version 7.
23 Q. And I think you told us earlier that that came out in 2011.
24 A. Correct.
25 Q. How do the standards of care get decided?

Exhibit

1 IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
2 CENTRAL DIVISION

3 DYLAN BRANDT, et al.,

4 Plaintiffs,
v. No. 4:21CV00450 JM
5
October 17, 2022
6 Little Rock, Arkansas
8:59 AM
7 LESLIE RUTLEDGE, et al.,

8 Defendants.

9 **TRANSCRIPT OF BENCH TRIAL - VOLUME 1**
BEFORE THE HONORABLE JAMES M. MOODY, JR.,
10 UNITED STATES DISTRICT JUDGE

11
APPEARANCES:
12
On Behalf of the Plaintiffs:
13
MR. CHASE STRANGIO, Attorney at Law
14 MS. LESLIE COOPER, Attorney at Law
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22 1870 Embarcadero Road
Palo Alto, California 94303
23

24 Appearances Continuing...

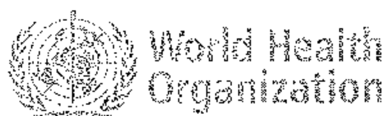
25

1 understands for HIPAA reasons and otherwise, the medical
2 records aren't ever going to be made available to them. So
3 you're talking about exhibits that I might receive during the
4 course of the hearing that have not previously been stipulated
5 to or admitted and how those make their way, I guess, the same
6 way the other ones did, that you decide once they've been
7 admitted that if you want to share, you do so. I don't know
8 how else to handle that.
9 MS. LAND: Would it be okay if the parties conferred
10 about whether to do that at the each of each day or at the end
11 of the trial itself?
12 THE COURT: That's not up to me. Yes, in short
13 answer. I'm not sure I get involved in that other than if I
14 ruled that admissible exhibits that haven't been sealed are
15 available to the media, however those get to the media is up to
16 you guys, and I don't generally get involved in that.
17 MS. LAND: Understood. Thank you.
18 THE COURT: Thank you. Anything other than that?
19 MS. LAND: No, Your Honor.
20 THE COURT: Call your first witness.
21 MS. COOPER: Thank you, Your Honor. We will call
22 Dr. Dan Karasic as our first witness.
23 **DAN KARASIC, PLAINTIFFS' WITNESS, DULY SWORN**
24 DIRECT EXAMINATION
25 BY MS. COOPER:

1 THE COURT: You don't have to ask. Just get up and
2 move and I'll know why. I'm sorry, Ms. Cooper, I've completely
3 blown up your start.
4 MS. COOPER: Not at all, Your Honor. I would like
5 to just bring out a couple of points on the witness's
6 qualifications and then can move on to his opinions.
7 BY MS. COOPER:
8 Q Dr. Karasic, have you treated patients with gender
9 dysphoria during your career?
10 A Yes, I have.
11 Q Approximately how many patients with gender dysphoria
12 have you treated?
13 A I can't give a precise number, but thousands of patients
14 over 30 years.
15 Q Of those patients, did they include adolescents with
16 gender dysphoria?
17 A Yes.
18 Q Can you give an estimate of the number of adolescents
19 you've treated with gender dysphoria?
20 A I would say in the hundreds.
21 Q Thank you.
22 Your Honor, I would move to have Dr. Karasic qualified as
23 an expert in psychiatry and specifically the treatment of
24 gender dysphoria in adolescents and adults.
25 THE COURT: Ms. Cooper, I don't usually receive an

1 THE COURT: So it's not a specific age because that
2 varies, but those who would be starting puberty to 18?
3 THE WITNESS: Right. So typically it's defined
4 as --
5 THE COURT: You've answered what I needed. I just
6 didn't know what bracket to put adolescents in for purposes of
7 this case. Thank you.
8 THE WITNESS: The DSM lumps adolescents and adults
9 into the one diagnosis.
10 BY MS. COOPER:
11 Q How is the DSM used by mental health professionals in
12 caring for patients?
13 A The DSM is a categorization that's used by health
14 professionals to make a mental health diagnosis and it's also
15 used in research.
16 Q And have you diagnosed patients with gender dysphoria?
17 A Yes.
18 Q Approximately how many?
19 A I would say in the thousands.
20 Q Could you summarize the diagnostic criteria for gender
21 dysphoria, just in general terms?
22 A Broad summary, it's someone who has a gender
23 incongruence, a difference between their experience or
24 expressed gender and their sex assigned at birth, their gender
25 assigned at birth that has lasted at least six months, there

Exhibit



Frequently Asked Questions

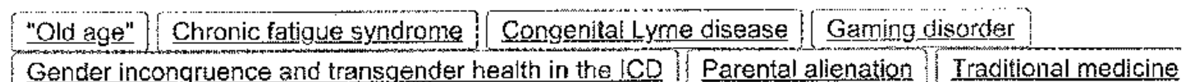
[Importance of ICD]

[ICD-11 Implementation]

[COVID-19 Emergency ICD Codes]

[Proposal Platform]

Frequently discussed topics



Gender incongruence and transgender health in the ICD

What is the ICD?

The International Classification serves to record and report health and health-related conditions globally. ICD ensures interoperability of digital health data, and their comparability. The ICD contains diseases, disorders, health conditions and much more. The inclusion of a specific category into ICD depends on utility to the different uses of ICD and sufficient evidence that a health condition exists.

ICD-11 and Gender Incongruence

The 11th edition of the International Statistical Classification of Diseases and Related Health Problems (ICD-11). The newly revised ICD-11 codes includes new changes to reflect modern understanding of sexual health and gender identity.

What does the ICD revision aim to do for transgender health?

ICD-11 has redefined gender identity-related health, replacing outdated diagnostic categories like ICD-10's "transsexualism" and "gender identity disorder of children" with "gender incongruence of adolescence and adulthood" and "gender incongruence of childhood", respectively. Gender incongruence has been moved out of the "Mental and behavioural disorders" chapter and into the new "Conditions related to sexual health" chapter. This reflects current knowledge that trans-related and gender diverse identities are not conditions of mental ill-health, and that classifying them as such can cause enormous stigma.

Inclusion of gender incongruence in the ICD-11 should ensure transgender people's access to gender-affirming health care, as well as adequate health insurance coverage for such services. Recognition in the ICD also acknowledges the links between gender identity, sexual behaviour, exposure to violence and sexually transmitted infections.

What is Gender Incongruence?

The bulk of the changes centered around the moving of "gender incongruence" from a classification of mental health to one of sexual health. In 2020, we have a better understanding of the issues surrounding this condition, and they are not related to a mental health condition. Treating gender incongruence in a mental health chapter was causing additional stigma for an already stigmatized condition. WHO officials added the hope that adding this condition to a sexual health chapter of the ICD codes would "help increase access to care for health interventions" and "destigmatize the condition."

What is transgender and what are the main health concerns of transgender people?

Transgender people share many of the same health needs as the general population, but may have other specialist health-care needs, such as gender-affirming hormone therapy and surgery. However, evidence suggests that transgender people often experience a disproportionately high

burden of disease, including in the domains of mental, sexual and reproductive health. Some transgender people seek medical or surgical transition, others do not.

What is gender-affirmative health care?

Gender-affirmative health care can include any single or combination of a number of social, psychological, behavioural or medical (including hormonal treatment or surgery) interventions designed to support and affirm an individual's gender identity.

Exhibit 10

All Policies

Mental Health Care Services by Family Physicians (Position Paper)

EXECUTIVE SUMMARY

Mental illness is highly prevalent in the United States and is associated with an increased risk of morbidity and mortality. There are significant gaps in the provision of mental health care services in the U.S., especially related to vulnerable populations. Family physicians are well-equipped to provide mental health services and are one of the primary sources for mental health care in the U.S. The American Academy of Family Physicians (AAFP) supports the following:

- Family physicians are well-prepared to provide many mental health services and should continue to lead and participate in these services to improve access, quality, and outcomes.
- Family physicians should work with behavioral and mental health professionals whenever possible to ensure the best care for their patients. This can range across a continuum, including collaboration and partnerships, co-locating services, or even full integration within one single care plan.
- Graduate medical education in family medicine emphasizes the direct link between physical and mental health, and should continue to offer behavioral and mental health training as part of the core curriculum.
- Family physicians should educate themselves about mental health practices, including staying up-to-date on screening recommendations for mental health; behavioral health and primary care integration models; trauma-informed care, telemedicine and telepsychiatry; and mental health disparities and high-risk populations.
- Family physicians should advocate for the elimination of the stigma that accompanies poor mental health, as well as supp policies that improve access to behavioral and mental health services.
- Advocating for the maintenance and expansion of state, federal, and private insurance funding of mental health care servic for all.
- Advocating for the establishment of payment mechanisms that adequately reimburse primary care physicians for providin mental health care services; and allows adequate funding of mental health care services provided in co-located practices to ensure its continued availability in the primary care physician's office.
- The development of new treatment strategies to increase the number of patients who receive appropriate treatment and follow-up through both primary care and mental health specialty care providers, and through the use of new technologies, such as telehealth.

BACKGROUND

Mental illness, which includes a range of mental health conditions that affect one's mood, thinking, and behavior, is one of the most pervasive causes of disease and disability worldwide. The prevalence of mental illness has important public health ramifications, affecting roughly 20% of all adults,[1] and is the leading cause of disability in the U.S., accounting for 18.7% of years of life lost to disability and premature mortality.[2] While mental illness is common in all parts of society, there are disparities, with American Indian and Alaska Natives (28.3%) experiencing higher rates than white (19.3%), black (18.6%), Hispanic (16.3%), or Asian (13.9%) adults.[1] Mental illness has a substantial economic impact, accounting for $179 billion in health care spending in 2014, which is projected to increase to $238 billion in 2020.[3]

Challenges exist for providing high-quality mental health care services in the U.S., mainly arising from the fragmentation of medical care and mental health care.[4] Mental health services are not distributed evenly throughout the U.S. and many communities lack access to these services.[5] Roughly two-thirds of primary care physicians are unable to connect their patients to outpatient mental health services.[6] This results in the need for primary care physicians to assume a leading role in the management of mental health

care services.[5] Primary care physicians serve as primary managers of psychiatric disorders in one-third of their patient panels[5] and two-thirds of patients with depression receive treatment for their depression in the primary care setting.[5]

Family medicine, which promotes the integration of the behavioral and physical models of illness, serves a vital role in providing mental health care services. Transformations within primary care, most notably the patient-centered medical home (PCMH), have called for reintegration of mental health care into routine comprehensive care through a team-based approach.[7-9] Integration can take place across a continuum, including collaboration and partnerships, co-locating services, or full integration within one single care plan.[10] The current lack of integration is a barrier to improving the quality, outcomes, and efficiency of care delivery for those struggling with both mental and physical illness.[11,12]

This paper explores the various issues family physicians face regarding mental health and mental health care services, clarifies the family physician's role, and provides direction to the AAFP to advocate for a better system for addressing mental health in the U.S. The paper covers topics related to: incorporating mental health care services in primary care; health disparities and high-risk populations; tobacco use as a risk factor for excess morbidity and mortality in the population experiencing mental illness; and payment.

ROLE OF THE FAMILY PHYSICIAN

While psychiatric and other mental health professionals can play an important role in the provision of high-quality mental health care services, primary care physicians are the main providers for the majority of patients. Most people with poor mental health will be diagnosed and treated in the primary care setting.[3] Mental illness also complicates other medical conditions, making them more challenging and more expensive to manage.[13] Together, this makes mental health an important issue for primary care physicians.

Family physicians are well-positioned to address their patient's mental health issues. The behavioral sciences and mental health are central tenets of the specialty of family medicine,[14] and family physicians receive high-quality training in these areas. The Residency Review Committee of the Accreditation Council for Graduate Medical Education (ACGME) for Family Medicine has stringent standards for education in family medicine residencies for mental health, including that residency programs: have faculty dedicated to the integration of behavioral health; teach residents to diagnose, manage, and coordinate care for common mental illnesses and behavioral issues in patients of all ages; require that residents demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and social-behavioral sciences, and their application to patient care; and structure their curriculum so that behavioral health is integrated within student's total educational experience.[15]

INCORPORATING MENTAL HEALTH SERVICES IN PRIMARY CARE

Screening for Mental Illness

Screening for mental illness is not new to family medicine but has more recently been linked to quality metrics and payment. Screening for mental illness can be an important strategy for decreasing morbidity,[16] as well as preventing adverse maternal and child health outcomes associated with perinatal depressive symptoms, postpartum depression, or maternal suicide.[17-20] While important, screening in a busy practice can seem overwhelming, but practices can leverage technology, empower staff, and utilize wellness visits to complete this screening.[21]

Family physicians should be aware of screening recommendations for their patients, recognizing that identification of mental health issues is integral to ensuring appropriate treatment and reduction of complications. Mental health clinical recommendations and guidelines developed or endorsed by the AAFP are outlined on the AAFP's website (http://www.aafp.org/patient-care/browse/topics.tag-mental-health.html).

Primary Care and Behavioral Health Integration

Integrating mental health into primary care settings, as well as the blending of primary and preventive medicine into traditional mental health settings, represents a more holistic approach to treatment than the traditional consultative and referral models. Integrating primary care and mental health services increases access for patients by making mental health services available in their regular primary care clinics. When integrated into primary care, mental health providers can impact the care of more patients than in the specialty mental health referral sector.[22] In the primary care setting, mental health providers take on a more consultative and team-based role and focus on helping primary care providers treat mental health disorders. In this context, mental health providers typically reach more patients, and have shorter and more problem-focused encounters than in the context of traditional specialty mental health.

Collaborative Care – A model for Primary Care and Mental Health Integration

The Collaborative Care Model, supported by various organizations including the American Psychiatric Association, is a model for the successful integration of primary care and behavioral and mental health.[23] At its core, the idea of collaborative care is anchored in team-based care, often in the context of a medical home, and steered by primary care physicians. It involves behavioral health specialists and consulting mental health professionals delivering evidence-based care that is patient-centered. Evaluations of this model of care are ongoing, particularly in the adult population.

The collaborative care model includes four core elements: 1) team driven, 2) population focused, 3) measurement guided, and 4) evidence based. These four elements, when combined, can allow for a fifth guiding principal to emerge—accountability and quality improvement. Collaborative care is team-driven, led by a primary care clinician with support from a "care manager" and consultation from a psychiatrist who provides treatment recommendations for patients who are not achieving clinical goals. Other mental health professionals can contribute to the Collaborative Care Model. Collaborative care is population focused, using a registry to monitor treatment engagement and response to care. Collaborative care is measurement guided with a consistent dedication to patient-reported outcomes and it utilizes evidence-based approaches to achieve those outcomes. Care remains patient centered with proactive outreach to engage, activate, promote self-management and treatment adherence, and coordina services.[23]

Telemedicine and Telepsychiatry

Telemedicine is the process of providing health care from a distance using technology. Telepsychiatry, a subset of telemedicine, can involve either direct or indirect interaction between a psychiatrist and the patient, where a psychiatrist supports a primary care physician and other health care providers. Several telehealth models exist for providing mental health services. A promising model is Project ECHO (Extension for Community Healthcare Outcomes). A model such as this seeks to enhance access to mental health and substance-use disorder treatment via remote and telehealth training and practice support for primary care clinicians, particularly in rural and underserved areas.[24,25] Telemedicine for mental health is a growing interest in primary care and telehealth initiatives for mental health care are expanding rapidly. While the research is limited on this topic, there are a growing number of studies assessing the benefits, comparative effectiveness with face-to-face visits, and cost comparisons. Family physicians who wish to integrate mental health care services in their practice, but have limited access, should consider learning more about this topic.

Trauma-informed Care

An estimated 60% of adults in the U.S. have experienced a traumatic event at least once in their lives.[26] Exposure to trauma, such as intimate partner violence, sexual abuse, rape, neglect, terrorism, war, natural disasters, and street violence predisposes those affected to poor physical and mental health outcomes.[27]

Trauma-informed care, an approach to engaging individuals with a history of trauma that recognizes their traumatic experiences, and how it affects their lives, is a promising practice that may facilitate healing and help prevent the consequences of exposure to trauma.[28-32] The principles of trauma-informed care include: realizing that there is a high prevalence of trauma and it has serious effects; recognizing the signs and symptoms of trauma; responding to the high prevalence by integrating knowledge about trauma into practices, procedures, and policies; and avoiding retraumatizing individuals by using best-practices in screening and history taking.[27]

While still in its infancy in family medicine, trauma-informed care is gaining support and evidence of its benefits are accumulating.[33] Family physicians who have learned about trauma-informed care have increased measurements of "patient-centeredness" after completing a continuing medical education (CME) course.[34] Family physicians will undoubtedly hear more about trauma-informed care and should take advantage of training opportunities in its principles and practice.[35]

HEALTH DISPARITIES AND HIGH-RISK POPULATIONS

Health Disparities

While mental health conditions can affect everyone, regardless of culture, race, ethnicity, gender or sexual orientation, some populations experience those conditions at a higher rate.

- American Indian and Alaska Natives (28.3%) experience higher rates of mental illness than white (19.3%), black (18.6%), Hispanic (16.3%), or Asian (13.9%) adults.[1]
- Individuals from the lesbian, gay, bisexual, transgender, and questioning (LGBTQ) community are two or more times as likely as heterosexual individuals to have a mental health condition[1] and LGBTQ youth are two to three times more likely to attempt suicide than heterosexual youth.[1]
- Nearly one-fifth (18.5%) of the veterans who returned from serving in either Iraq or Afghanistan suffer from either major depression or post-traumatic stress disorder.[36]
- The prevalence of mental illness is similar for individuals living in either rural or metropolitan areas, but the mental health care needs are more often unmet in rural communities due to inadequate services.[37]

Disparities in mental health illness and mental health care are related to coverage and availability of care, quality of care, rates of health insurance, stigma, cultural insensitivity, racism, bias, homophobia, discrimination in treatment settings, and language barriers.[1]

College Students

Approximately 20 million students are enrolled in U.S. colleges and universities.[38] Mental health concerns, such as non-suicidal self-injury and serious suicidal ideation, have risen in this population over the past several years.[39] According to the Center for Collegiate Mental Health's 2017 Annual Report, 52.7% of students attended counseling for mental health concerns; 34.2% took a medication for mental health concerns; 9.8% were hospitalized for a mental health concern; 27% purposely injured themselves without suicidal intent; and 34.2% seriously considered attempting suicide, with 10% making a suicide attempt.[39] In fact, some data suggest that suicide may be the most common cause of death in college students.[40]

Attention-deficit/hyperactivity disorder (ADHD) is another prevalent disorder in college students that family physicians may encounter. ADHD's prevalence is estimated to be between 2-8% among college students, and this condition is frequently associated with other psychiatric comorbidities and increases individuals' risk of psychosocial and substance-use problems.[41]

TOBACCO USE – A RISK FACTOR FOR EXCESS MORBIDITY AND MORTALITY

Tobacco use is prominent among individuals living with mental illness. Thirty-six percent of adults with any mental illness use tobacco products, compared with 25.3% for adults without a mental illness.[42] In addition, people who have any mental illness are only half as likely to quit smoking compared to individuals without a mental illness.[43] One study found that nearly half of all deaths were tobacco-related for persons who received substance abuse services, or who received both substance abuse and mental health services.[44] Therefore, addressing tobacco addiction among individuals living with mental illness is an important strategy for decreasing preventable mortality and morbidity among individuals living with a mental illness.

The AAFP has position papers that detail substance abuse and addiction and tobacco prevention and cessation.

PAYMENT

Historically, primary care physicians have encountered barriers to receiving full reimbursement for office visits for mental health diagnoses. This limitation in reimbursement interfered with the family physician's ability to offer comprehensive care and management of mental health conditions, as well as the ability to integrate, from a business perspective, with behavioral health services. However, new coverage policies adopted by the Centers for Medicare & Medicaid Services (CMS) are more promising and may incentivize primary care physicians to provide treatment for mental and behavioral health conditions.[45] These policies, effective January 1, 2017, emphasize collaborative care, where primary care physicians are expected to work in partnership with a behavioral health care manager, and consult with mental health specialists. While targeting populations with Medicare, these policies may also encourage private insurers to offer similar options and may incentivize more family physicians to offer behavioral and mental health care to other populations.

Health care for all people with mental illness should be "affordable, nondiscriminatory, and includes coverage for the most effective and appropriate treatment."[46] Coverage for mental illness should be equal in scope to coverage for other illnesses and all clinically-effective treatments appropriate to the needs of individuals with mental illness should be covered.

CONCLUSION

Family physicians play an important role in the provision of mental health care services in the U.S. and are well trained to provide many types of mental health care services. It is imperative that family physicians work to integrate with mental and behavioral health care providers to better meet their patients' needs when possible. A variety of models and resources exist to assist them with filling the existing gaps in the provision of mental health care services in the U.S., especially related to vulnerable populatior In this manner, family physicians can work to meet both the physical and mental health care needs of their patients.

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(2001) (2018 COD)

See Also

Mental Health, Physician Responsibility

Mental Health, Parity in Coverage for Patients

School Safety and Student Mental Health

Exhibit

1 IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
2 AT TACOMA

3

C.P., by and through his parents, PATRICIA PRITCHARD AND NOLLE PRITCHARD; and PATRICIA PRITCHARD,	)	
Plaintiffs,	)	No. 3:20-cv-06145-RJB
vs.	)	
BLUE CROSS BLUE SHIELD OF ILLINOIS,	)	
Defendant.	)	

4 5 6 7 8 9 10

11 REMOTE
12 VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION OF
KEVIN HATFIELD, M.D.
13 June 14, 2022

14 Taken remotely
Witness location: Seattle, Washington

15

16

17

18

19

20

21
KATIE J. NELSON, RPR, CCR #2971
22 NELSON COURT REPORTERS, INC.
6513 132nd Avenue NE, #184
23 Kirkland, Washington 98033
(425) 866-4250
24 production@nelsonreporters.com

25

1 Q. -- that you've been in practice?
2 A. -- correct.
3 Q. How long have you been treating people with --
4 needing gender treatment?
5 A. I started seeing patients when I was in residency
6 in '99, but they were adults, and I started seeing younger
7 patients probably in 2004, 2005.
8 Q. Do you ever not recommend a puberty blocker for an
9 individual?
10 A. Contextually I would say I give it as an option to
11 any patient that is in their adolescence and they still have
12 additional changes that might occur if their body is
13 producing a hormone that they're questioning the benefit of,
14 so I think I will often mention it as a helpful tool. And
15 there are some patients who I say, you know, it's not
16 something we need to do by force, it is optional, but here
17 are the reasons that we could consider using it and here are
18 reasons why you may not want to and I just sometimes will
19 leave it up to the patient, but that is more unusual than
20 typical.
21 Q. That they don't want to use the puberty blocker,
22 you mean?
23 A. I'm sorry. I missed the beginning of the question.
24 Q. Yeah. You said it's actually unusual that a
25 patient will not want to use the puberty blocker?

Exhibit

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his parents, PATRICIA PRITCHARD AND NOLLE PRITCHARD; and PATRICIA PRITCHARD, Plaintiffs,	No. 3:20-cv-06145-RJB
vs.	
BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendant.	

REMOTE
VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION OF
SHARON BOOKER, MA, LMHC
May 6, 2022

Witness location: Poulsbo, Washington

KATIE J. NELSON, RPR, CCR #2971
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1 that he presented with depression?
2 A. Well, it's difficult because dysphoria is a form of
3 depression, so that's why I said "other" to be more specific
4 that it was for dysphoria as far as the kind of depression.
5 Q. But you diagnosed him as presenting with symptoms
6 of depression. This was a -- your diagnosis, in other
7 words, right?
8 A. No, I did not diagnose him with depression. You
9 can see by the diagnosis, I did not. I checkmarked that
10 there was some symptoms of depression, but they are more
11 accounted for by dysphoria. Did not -- did not diagnose him
12 with depression, did not meet that -- those criteria.
13 Q. Okay. So just so I'm understanding, this -- the
14 checkboxes here do not indicate a diagnosis?
15 A. Right.
16 Q. They indicate present -- that the client -- that
17 your client is presenting with certain symptoms?
18 A. Symptoms or problems --
19 Q. Symptoms or problems?
20 A. -- has them.
21 Q. Okay. Thank you.
22 A. Issues --
23 Q. For C.P. --
24 A. It could be issues -- sorry.
25 Q. Thank you.

Exhibit

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

[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.

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[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

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[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

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[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").

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[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

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[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.

[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

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[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

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[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.