From: miriam grossman <miriamgrossmanmd@hotmail.com>
To: Andre Van Mol <95andrev@gmail.com>, Andrew.Sheeran@ahca.myflorida.com
Cc: Weida Jason <Jason.Weida@ahca.myflorida.com>, Van Meter Quentin <kidendo@comcast.net>, "Sheeran, Andrew" <Andrew.Sheeran@ahca.myflorida.com>
Subject: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)
Sent: 2022-07-10T03:08:29Z

Hi everyone,
I just wanted to say how much I enjoyed the two hours. I was so pleased to hear a huge majority speaking in favor. They were such salt of the earth, patriotic, common sense people, I loved it and loved how they cheered each time de Santis was mentioned. I did not hear most of what you guys on the panel said due to a hitch with the audio. I was prepared to be challenged and put on the spot but the clock ticked and ticked and…nothing. Where did all the opposition go? Weren't you expecting a bigger turnout? That one church really brought a lot of people! I was smiling ear to ear by the end.

To which state do we go next? I'm ready.

Miriam

Sent from my iPad

> On Jul 8, 2022, at 12:29 AM, Andre Van Mol <95andrev@gmail.com> wrote:
>
> Late morning sounds good. BTW, I got from Paul Hruz his classic takedown of the p.10 AAP letter slogan that randomized controlled trials may be unethical in GAT.
> "It is often argued that conducting randomized controlled trials in the field of gender medicine would be unethical. This is based upon the false premise that the control group would receive no specific therapy. However, in scientific investigation all variables except the independent variable being tested are kept constant in both experimental and control groups. Thus, although members of the control group do not receive the intervention being studied, they are provided with all other aspects of treatment indicated for the condition; that is, they receive standard care. There are numerous means of psychological support for anxiety, depression, and other comorbidities associated with gender dysphoria. Coping skills can be developed in both treatment arms."

Andre

> On Jul 7, 2022, at 8:13 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:

Got it. Thanks. We can discuss tomorrow. I got a conference room at the Agency

Pl. Trial Ex. 307

for us if you want to come over before we head out to the hearing. Come at your leisure. Perhaps mid to late morning? We'll be heading over the hearing in the same vehicle (rental van) around 2:20.

Get Outlook for iOS

From: Andre Van Mol <95andrev@gmail.com>
Sent: Thursday, July 7, 2022 10:23:28 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>; Van Meter Quentin <kidendo@comcast.net>; Grossman Miriam <miriamgrossmanmd@hotmail.com>; Sheeran, Andrew <Andrew.Sheeran@ahca.myflorida.com>
Subject: Re: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)

Here is my rebuttal of the AAP statement. Yellow highlights and usually embedded comments. I'm doing this from inside a plane on the tarmac using my iPhone hot spot, so I hope it works. :)

Andre

> On Jul 7, 2022, at 3:10 PM, miriam grossman <miriamgrossmanmd@hotmail.com> wrote:
>
> Hi Jason
> Thanks for forwarding. I skimmed through and don't see any surprises. Please refer audience questions about standards of care to the other docs who are more articulate on this subject than I.
> Miriam

Sent from my iPhone

> On Jul 7, 2022, at 5:25 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:
>
> **PRIVILEGED & CONFIDENTIAL**
> **ATTORNEY WORK PRODUCT PROTECTED**
>
> Andre, Quentin, and Miriam,
>
> Please see the below and attached. Today, the American Academy of Pediatrics and its Florida

Chapter have submitted this white paper responding to the GAPMS report and the proposal rule. I encourage you to read it.

Thanks,
Jason

From: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Sent: Thursday, July 7, 2022 5:11 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>
Subject: FW: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

---

From: Scott Van Deman <communications@fcaap.org>
Sent: Thursday, July 7, 2022 1:59 PM
To: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Cc: Hudson, Jeff <JHudson@aap.org>; Alicia E. Adams, Esq. <master@fcaap.org>
Subject: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

To whom it may concern:

Thank you for the opportunity to provide commentary to the Agency for Healthcare Administration on Medicaid rules currently being considered.

Attached is a joint letter from The American Academy of Pediatrics and the Florida Chapter of the American Academy of Pediatrics pertaining to the proposed rule concerning Medicaid's coverage of gender affirming care. This letter also has been submitted electronically through the feedback form at the Florida Department of State public notice number 25979915.

I am requesting that you please acknowledge receipt of this communication via return email.

Thank you once again, and please let me know if you have any questions.

Sincerely,

Scott VanDeman
Communications Coordinator
Florida Chapter of American Academy of Pediatrics, Inc.
Call: 850-224-3939, ext. 1005 |Text: 850-772-0654| Fax: 912-452-9050
Email: svandeman@fcaap.org |
Website: fcaap.org
Mail: 1400 Village Square Blvd., #3-87786, Tallahassee, FL 32312

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From: Brackett, Matt
Subject: FW: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)
To: ""Chen"","" Nai; Nai.Chen@ahca.myflorida.com
Sent: July 14, 2022 9:48 AM (UTC-04:00)
Attached: AAP-FCAAP Comment Letter_Medicaid Coverage for Gender-Affirming Care (FINAL).VanMolCritique.pdf

---

From: Weida, Jason <Jason.Weida@ahca.myflorida.com>
Sent: Thursday, July 7, 2022 11:11 PM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: Fwd: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)

Get Outlook for iOS

From: Andre Van Mol <95andrev@gmail.com>
Sent: Thursday, July 7, 2022 10:23:28 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>; Van Meter Quentin <kidendo@comcast.net>; Grossman Miriam <miriamgrossmanmd@hotmail.com>; Sheeran, Andrew <Andrew.Sheeran@ahca.myflorida.com>
Subject: Re: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)

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>
> Hi Jason
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> Miriam
>
> Sent from my iPhone
>
> > On Jul 7, 2022, at 5:25 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:
> >
> > **PRIVILEGED & CONFIDENTIAL**
> > **ATTORNEY WORK PRODUCT PROTECTED**
> >
> > Andre, Quentin, and Miriam,
> >
> > Please see the below and attached. Today, the American Academy of Pediatrics and its Florida Chapter have submitted this white paper responding to the GAPMS report and the proposal rule. I encourage you to read it.
> >
> > Thanks,
> > Jason

Pl. Trial Ex. 307

From: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Sent: Thursday, July 7, 2022 5:11 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>
Subject: FW: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

From: Scott Van Deman <communications@fcaap.org>
Sent: Thursday, July 7, 2022 1:59 PM
To: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Cc: Hudson, Jeff <JHudson@aap.org>; Alicia E. Adams, Esq. <master@fcaap.org>
Subject: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

To whom it may concern:

Thank you for the opportunity to provide commentary to the Agency for Healthcare Administration on Medicaid rules currently being considered.

Attached is a joint letter from The American Academy of Pediatrics and the Florida Chapter of the American Academy of Pediatrics pertaining to the proposed rule concerning Medicaid's coverage of gender affirming care. This letter also has been submitted electronically through the feedback form at the Florida Department of State public notice number 25979915.

I am requesting that you please acknowledge receipt of this communication via return email.

Thank you once again, and please let me know if you have any questions.

Sincerely,

Scott VanDeman
Communications Coordinator
Florida Chapter of American Academy of Pediatrics, Inc.
Call: 850-224-3939, ext. 1005 |Text: 850-772-0654| Fax: 912-452-9050
Email: svandeman@fcaap.org | Website: fcaap.org
Mail: 1400 Village Square Blvd., #3-87786, Tallahassee, FL 32312

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<image006.png><image007.png><AAP-FCAAP Comment Letter_Medicaid Coverage for Gender-Affirming Care (FINAL).pdf>

Re: Yale (Privileged & Confidential)

miriam grossman <[redacted]>
Wed 7/20/2022 6:53 PM

To: Weida, Jason <Jason.Weida@ahca.myflorida.com>

Cc: Tamayo, Josefina <Josefina.Tamayo@ahca.myflorida.com>;mjazil@holtzmanvogel.com <mjazil@holtzmanvogel.com>;gperko@holtzmanvogel.com <gperko@holtzmanvogel.com>

Hi, I can do Monday at 10am but is this about the Alstott letter? Is it still important that I review it? I'm very pressed for time.
Miriam

Sent from my iPad

> On Jul 20, 2022, at 3:30 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:
>
> Hi Miriam,
>
> No problem. Would you be available for a quick call at some point the morning of Monday, July 25? We are trying to wrap up and it would be helpful to connect with you on Monday morning, if you can make that work?
>
> Thanks!
>
> Jason
>
> ---
>
> **From:** miriam grossman <[redacted]>
> **Sent:** Tuesday, July 19, 2022 10:53 PM
> **To:** Andre Van Mol <95andrev@gmail.com>; Weida, Jason <Jason.Weida@ahca.myflorida.com>
> **Cc:** Van Meter Quentin <kidendo@comcast.net>; Tamayo, Josefina <Josefina.Tamayo@ahca.myflorida.com>; mjazil@holtzmanvogel.com; gperko@holtzmanvogel.com
> **Subject:** Re: Yale (Privileged & Confidential)
>
> Jason,
>
> I can't get to any of this until next week, sorry.
>
> [redacted]
>
> Miriam Grossman MD
> Board-Certified in Child, Adolescent and Adult Psychiatry

Pl. Trial Ex. 307

From: Andre Van Mol <95andrev@gmail.com>
Sent: Tuesday, July 19, 2022 9:51 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>
Cc: Van Meter Quentin <kidendo@comcast.net>; miriam grossman <[redacted]>; Tamayo, Josefina <Josefina.Tamayo@ahca.myflorida.com>; mjazil@holtzmanvogel.com <mjazil@holtzmanvogel.com>; gperko@holtzmanvogel.com <gperko@holtzmanvogel.com>
Subject: Re: Yale (Privileged & Confidential)

By the way, Friday at 7 or 8 AM Pacific time start time would work for me.

Andre

Sent from my iPhone

> On Jul 19, 2022, at 2:33 PM, Andre Van Mol <95andrev@gmail.com> wrote:
>
> Hi, Jason and team.
>
> 47 pages. Yikes. I'll see what I can do this evening. Quentin may well be on a flight back from Europe in the next day or two. Not sure what Miriam's busy schedule looks like. My oldest gets married this Saturday, so the week is a bit full, and I am on vacation next week. But, I'll do what I can.
>
> Andre
>
> Sent from my iPhone
>
> > On Jul 19, 2022, at 12:33 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:
> >
> > **PRIVILEGED & CONFIDENTIAL**
> > **ATTORNEY WORK PRODUCT PROTECTED**
> >
> > Andre, Quentin, and Miriam,

Please see the attached report from Yale. You may or may not have seen this one already. Would you be able to review it and give me your preliminary thoughts? Happy to set up a call if that's what you prefer. If I could get some high-level comments on Yale's report by 2:00 PM Eastern tomorrow I would be very grateful.

In addition, you will each be overnighted a binder that contain a handful of the substantive comments (e.g., Yale, APP, Endocrine Society) that will be appended to a 17-page document summarizing the Agency's responses/positions with respect to the points raised in those substantive comments. Please review those materials as well so we can discuss as soon as you are able this week.

Thanks,
Jason

Jason C. Weida
Assistant Deputy Secretary
for Medicaid Policy & Quality

2727 Mahan Drive
Bldg 3 Room 2413
+1 850-412-4118 (Office)
+1 850-228-1898 (Cell)
Jason.Weida@ahca.myflorida.com

<Alstott et al FULL comment proposed rule re gender dysphoria ACCESSIBLE.pdf>

Received 6/13/2022
PR12154138

13 June, 2022

Invoice # 101

In the matter of supplying information for the Florida AHCA Generally Accepted Professional Medical Standard on Gender Dysphoria

Vendor- Van Meter Pediatric Endocrinology, P.C. TIN- 81-0618945

Dates of service- 5/1/2022- 5/17/2022

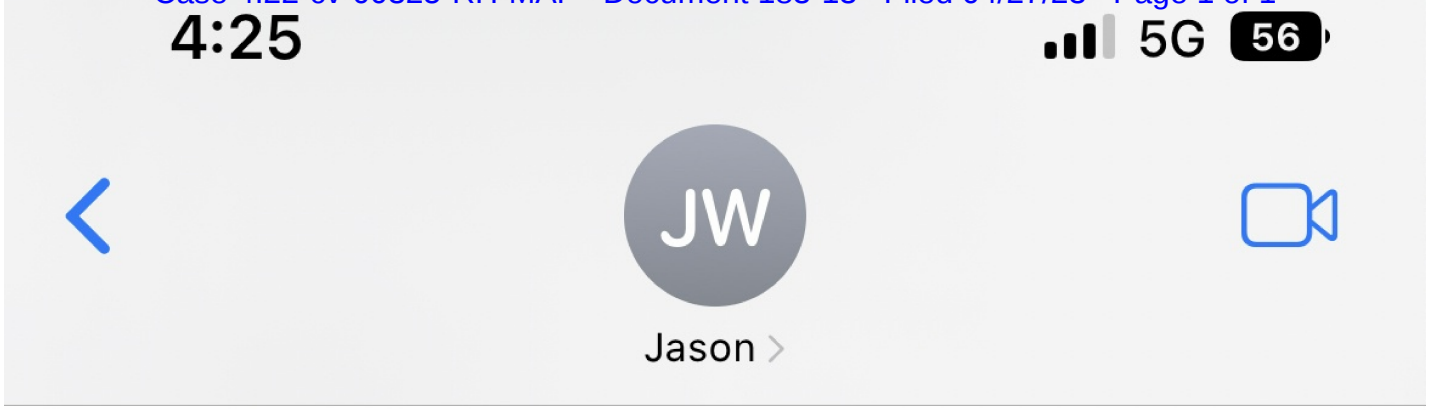
Itemization for Services Provided

5/1/2022	teleconference with AHCA staff	0.75 h
5/8/2022	creation of initial draft report	1.0 h
5/12/2022	rewriting of draft report	3.5 h
5/16/2022	revision of draft report vetting references	2.5 h
5/17/2022	review of final draft report	0.75 h
Total hours		8.5 h @$350.00/h
Total compensation due		**$2,975.00**

I certify that all costs and fees claimed for payment are accurate and were performed in furtherance of the Agreement between Van Meter Pediatric Endocrinology, P.C. and the Agency for Health Care Administration

Quentin L. Van Meter, M.D.
Pediatric Endocrinologist

Pl. Trial Ex. 307



Wed, Aug 10 at 9:14 AM

From Quentin:

"Tom Benton of Gainesville has agreed to speak at the Friday meeting. He should be calling you. His email address is notneb@bellsouth.com."

Andre Van Mol, MD
12860 Yanot Drive
Redding, CA 96003
Tel. 530-604-9370
95andrev@gmail.com
SSN 554-02-8856

Jason Weida
Florida Dept of Medicaid
Bldg 3 Room 2413
2727 Mahan Dr.
Tallahassee, FL. 32308

RE: Itemized charges for consulting, July 2022, Invoice # FL003A

August 11, 2022

Dear Mr. Weida,

Thank you and your team for the invitation to serve as a consultant for the state of Florida's Medicaid rules hearing regarding the Medicaid GAPMS document for gender dysphoria treatment. Please find below a listing of hours spent on the project for July 2022.

7/02/2022	(*2 hours*	*Reading and prep for rules hearing*) (*no charge*)
7/03/2022	3 hours	Reading and prep for rules hearing
7/04/2022	3 hours	Reading and prep for rules hearing
7/06/2022	1 hour	Teleconference with FL Medicaid team
7/07/2022	3 hours	Prep, e-consulting, evaluating and rebutting opposition letters
7/08/2022	7 hours	Group prep for rules hearing and rules hearing panel (Tallahassee)
7/19/2022	2.5 hours	Review/critique of Alstott letter contra Medicaid GAPMS report
7/21/2022	1 hour	Review/critique FL Medicaid Comment Summary for Rule & Responses
7/22/2022	0.5 hours	Teleconference with FL Medicaid team RE Rules, Comments, Responses

Total hours = 21 hours at $350 per hour

Total charges = $7,350

Andre Van Mol, MD

Pl. Trial Ex. 307

From: Pickle, Devona
Sent: Monday, August 22, 2022 11:31 AM EDT
To: \"\"Weida\"\",\"\" Jason; Jason.Weida@ahca.myflorida.com
CC: Dalton, Ann
Subject: GD Policy Transmittal
Attachments: Provider Alert GD Treatment 7-25-22_dp.docx - MB edits.docx, PT_2022-07_Non-Coverage_of_Gender_Dysphoria_08.22.2022.docx
Importance: High

Jason,

Here are the updated PT and provider alert for your review.

D.D. Pickle
(office) 850-412-4646

From: Dalton, Ann <Ann.Dalton@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:26 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>; Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Subject: Re: GD Policy Transmittal

Thanks. These look good. Please finalize and send to Jason for routing and approval.

Get Outlook for iOS

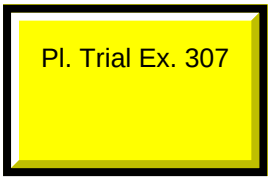
From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:14:10 AM
To: Dalton, Ann <Ann.Dalton@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>; Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Subject: FW: GD Policy Transmittal

Ann,

Here is the revised alert. I reattached the PT just to keep the two together. Nothing has changed in the PT.

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:11 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal



Are these changes sufficient.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:10 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

That's what I was hoping Ashley would update.

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:10 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

You're right, just realized that.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:09 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

No. But why eQ? Doesn't Magellan PBM authorize drugs?

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:08 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Did eQHealth change its name?

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:07 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Yep, I see I missed a plan and so did Ashley.

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:06 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: FW: GD Policy Transmittal

Hi, D.D.
Hold off on sending this to Ann. It needs some tweaking.

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:04 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Hi D.D. – my edits attached.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:54 AM
To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Ashley - Ann wants to include the 60-day language in the alert. Would you edit what I've added so it fits?

D.D. Pickle
(office) 850-412-4646

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:37 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Thanks, that is the only edit I have and nothing for the PA.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:36 AM

To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Good catch!

D.D. Pickle
(office) 850-412-4646

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:35 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

I added one thing to help clarify that these drugs will still be provided, just not for GD. Please let me know if you think this is unnecessary or adds confusion.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 9:28 AM
To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: GD Policy Transmittal

Good morning, Ashley,

Ann asked that I share the attached the policy transmittal with you to use in development of the provider alert. Matt had earlier drafted a PT that he will forward to you.

D.D. Pickle, Program Director
Canadian Prescription Drug Importation Program
Agency for Health Care Administration
Office - ***850-412-4646***
Medicaid Helpline - ***1-877-254-1055***

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

Florida Medicaid Health Care Alert Sign-Off Form

Provider Type(s): All Providers

Date: August 22, 2022

Alert Subject: Coverage of Treatment for Gender Dysphoria

Is this alert related to a billing or system change (including file maintenance and claims reprocessing)? ☐ Yes ☒ No

If yes, we will send to Fiscal Agent Operations for an additional 24-hour review.

If yes, please provide the tracking number:

Is this alert related to provider enrollment? ☐ Yes ☒ No

If yes, we will send to Fiscal Agent Operations for an additional 24-hour review.

Does this alert have Bureau Chief, ADS, or Director approval to bypass the review period? ☐ Yes ☒ No

If yes, please provide signatures or emails verifying authorization.

Does the alert refer the provider to another entity (ex. eQhealth, Medicaid Help Line, etc): ☐ Yes ☒ No

Entity (1) Referred to: _____ Referral method: ☐ Website ☐ Email ☐ Phone

Has entity been notified: ☐ Yes ☐ No

Entity (2) Referred to: _____ Referral method: ☐ Website ☐ Email ☐ Phone

Has entity been notified: ☐ Yes ☐ No

2727 Mahan Drive • Mail Stop #8
Tallahassee, FL 32308
AHCA.MyFlorida.com

Please make sure the entire message is included in the box below:
Please send Word document of form and the PDF of signed form to: Kelly.Cullen@ahca.myflorida.com

On August 21, 2022, changes to Rule 59G-1.050, Florida Administrative Code (F.A.C.) went into effect. These changes prohibit Florida Medicaid from reimbursing providers for the following services when used to treat gender dysphoria:

- Puberty blockers
- Hormones and hormone antagonists
- Sex reassignment surgery
- Any other procedures that alter primary or secondary sexual characteristics

For determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) guidelines, the services listed above do not meet medical necessity criteria as specified in Rule 59G-1.010, F.A.C.

To ensure safe discontinuation of puberty blockers or hormones and hormone antagonists for the treatment of gender dysphoria, or allow transition of payment to non-Medicaid funding sources, Florida Medicaid will honor any current prior authorization of prescribed outpatient drugs for the treatment of gender dysphoria through 60 days after the date of this alert (October 20, 2022). If the recipient's prior authorization expires during the 60-day period, providers should coordinate with the recipient's managed care plan or Magellan PBM to extend the prior authorization to cover the treatment through October 20, 2022.

For further information, the complete rule text can be found at the following source: Florida Medicaid General Policies.

Analyst – Matt Brackett	Date
	Date
AHC Administrator – D.D. Pickle	Date
Bureau Chief – Ann Dalton	Date

Comments:

Revised January 2017

From: Pickle, Devona
Subject: GD Policy Transmittal
To: ""Weida"","" Jason; Jason.Weida@ahca.myflorida.com
Cc: Dalton, Ann
Sent: August 22, 2022 11:32 AM (UTC-04:00)
Attached: Provider Alert GD Treatment 7-25-22_dp.docx - MB edits.docx, PT_2022-07_Non-Coverage_of_Gender_Dysphoria_08.22.2022.docx

Jason,

Here are the updated PT and provider alert for your review.

D.D. Pickle
(office) 850-412-4646

From: Dalton, Ann <Ann.Dalton@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:26 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>; Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Subject: Re: GD Policy Transmittal

Thanks. These look good. Please finalize and send to Jason for routing and approval.

Get Outlook for iOS

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:14:10 AM
To: Dalton, Ann <Ann.Dalton@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>; Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Subject: FW: GD Policy Transmittal

Ann,

Here is the revised alert. I reattached the PT just to keep the two together. Nothing has changed in the PT.

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:11 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Are these changes sufficient.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:10 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

That's what I was hoping Ashley would update.

Pl. Trial Ex. 307

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:10 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

You're right, just realized that.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:09 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

No. But why eQ? Doesn't Magellan PBM authorize drugs?

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:08 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Did eQHealth change its name?

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:07 AM
To: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Yep, I see I missed a plan and so did Ashley.

D.D. Pickle
(office) 850-412-4646

From: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:06 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Subject: FW: GD Policy Transmittal

Hi, D.D.
Hold off on sending this to Ann. It needs some tweaking.

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 11:04 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>

Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Hi D.D. – my edits attached.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:54 AM
To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Ashley - Ann wants to include the 60-day language in the alert. Would you edit what I've added so it fits?

D.D. Pickle
(office) 850-412-4646

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:37 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Thanks, that is the only edit I have and nothing for the PA.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:36 AM
To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

Good catch!

D.D. Pickle
(office) 850-412-4646

From: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Sent: Monday, August 22, 2022 10:35 AM
To: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>
Subject: RE: GD Policy Transmittal

I added one thing to help clarify that these drugs will still be provided, just not for GD. Please let me know if you think this is unnecessary or adds confusion.

From: Pickle, Devona <Devona.Pickle@ahca.myflorida.com>
Sent: Monday, August 22, 2022 9:28 AM
To: Peterson, Ashley <Ashley.Peterson@ahca.myflorida.com>
Cc: Brackett, Matt <Matt.Brackett@ahca.myflorida.com>

Subject: GD Policy Transmittal

Good morning, Ashley,

Ann asked that I share the attached the policy transmittal with you to use in development of the provider alert. Matt had earlier drafted a PT that he will forward to you.

D.D. Pickle, Program Director
Canadian Prescription Drug Importation Program
Agency for Health Care Administration
Office - ***850-412-4646***
Medicaid Helpline - ***1-877-254-1055***

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

August 22, 2022

Statewide Medicaid Managed Care (SMMC) Policy Transmittal: 2022-XX

Applicable to the **2018-2023 SMMC contract benefits** for:
- ☒ Managed Medical Assistance (MMA) and MMA Specialty
- ☐ Long-Term Care (LTC)
- ☐ Dental

Re: Non-Coverage of Gender Dysphoria Treatments

The Agency for Health Care Administration (Agency) is responsible for promulgating coverage requirements applicable to managed care plans through Florida Medicaid Coverage Policies, services listed in the associated Florida Medicaid fee schedules, and the Florida Medicaid State Plan, as well as plan communications specific to changes in federal and State law, rules or regulations and federal [Centers for Medicare & Medicaid Services] waivers applicable to this contract. (Attachment II, Section VI.A.1.a.) The purpose of this policy transmittal is to notify the managed care plan of a change to covered services and advise the managed care plan of its responsibilities for transition of care.

The Agency recently promulgated revisions to Rule 59G-1.050, Florida Administrative Code (F.A.C.), General Medicaid Policy, to create subparagraph (7), Gender Dysphoria. Effective August 21, 2022. Florida Medicaid no longer covers the following services for the treatment of gender dysphoria:

- Puberty blockers;
- Hormones and hormone antagonists;
- Sex reassignment surgeries; and
- Any other procedures that alter primary or secondary sexual characteristics.

For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed above do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C. (Rule 59G-1.050(7), F.A.C.)

To ensure the safe discontinuation of puberty blockers or hormones and hormone antagonists for the treatment of gender dysphoria, or allow transition of payment to non-Medicaid funding sources, the managed care plan must notify its subcontractors, providers, and enrollees receiving active treatment of the changes in coverage. In addition the managed care plan must honor any current prior authorization of prescribed outpatient drugs for the treatment of gender dysphoria through sixty (60) days after the date of this policy transmittal (October 20, 2022). If the enrollee's prior authorization expires during the sixty (60)-day period, the managed care plan will coordinate with the enrollee and the enrollee's prescriber to extend the prior authorization to cover the treatment through October 20, 2022.

If you have any questions, please contact your contract manager at (850) 412-4004.

2727 Mahan Drive • Mail Stop #8
Tallahassee, FL 32308
AHCA.MyFlorida.com

Facebook.com/AHCAFlorida
Twitter.com/AHCA_FL

Pl. Trial Ex. 307

Sincerely,

Tom Wallace
Deputy Secretary for Medicaid

TW/dvp

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

Florida Medicaid Health Care Alert Sign-Off Form

Provider Type(s): All Providers

Date: August 22, 2022

Alert Subject: Coverage of Treatment for Gender Dysphoria

Is this alert related to a billing or system change (including file maintenance and claims reprocessing)? ☐ Yes ☒ No

If yes, we will send to Fiscal Agent Operations for an additional 24-hour review.

If yes, please provide the tracking number:

Is this alert related to provider enrollment? ☐ Yes ☒ No

If yes, we will send to Fiscal Agent Operations for an additional 24-hour review.

Does this alert have Bureau Chief, ADS, or Director approval to bypass the review period? ☐ Yes ☒ No

If yes, please provide signatures or emails verifying authorization.

Does the alert refer the provider to another entity (ex. eQhealth, Medicaid Help Line, etc): ☐ Yes ☒ No

Entity (1) Referred to: _____ Referral method: ☐ Website ☐ Email ☐ Phone

Has entity been notified: ☐ Yes ☐ No

Entity (2) Referred to: _____ Referral method: ☐ Website ☐ Email ☐ Phone

Has entity been notified: ☐ Yes ☐ No

2727 Mahan Drive • Mail Stop #8
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Facebook.com/AHCAFlorida
Youtube.com/AHCAFlorida
Twitter.com/AHCA_FL
SlideShare.net/AHCAFlorida

Pl. Trial Ex. 307

Please make sure the entire message is included in the box below:
Please send Word document of form and the PDF of signed form to: Kelly.Cullen@ahca.myflorida.com

On August 21, 2022, changes to Rule 59G-1.050, Florida Administrative Code (F.A.C.) went into effect. These changes prohibit Florida Medicaid from reimbursing providers for the following services when used to treat gender dysphoria:

- Puberty blockers
- Hormones and hormone antagonists
- Sex reassignment surgery
- Any other procedures that alter primary or secondary sexual characteristics

For determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) guidelines, the services listed above do not meet medical necessity criteria as specified in Rule 59G-1.010, F.A.C.

To ensure safe discontinuation of puberty blockers or hormones and hormone antagonists for the treatment of gender dysphoria, or allow transition of payment to non-Medicaid funding sources, Florida Medicaid will honor any current prior authorization of prescribed outpatient drugs for the treatment of gender dysphoria through 60 days after the date of this alert (October 20, 2022). If the recipient's prior authorization expires during the 60-day period, providers should coordinate with the recipient's managed care plan or Magellan PBM to extend the prior authorization to cover the treatment through October 20, 2022.

For further information, the complete rule text can be found at the following source: Florida Medicaid General Policies.

Analyst – Matt Brackett	Date
	Date
AHC Administrator – D.D. Pickle	Date
Bureau Chief – Ann Dalton	Date

Comments:

Revised January 2017

Florida Medicaid

Estrogen		
Children		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	72	185
FY2018-19	87	212
FY2019-20	89	224
FY2020-21	151	391
Total	**399**	**1,012**
Adults		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	148	392
FY2018-19	168	486
FY2019-20	174	484
FY2020-21	223	688
Total	**713**	**2,050**

Puberty Blockers		
Children		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	15	59
FY2018-19	23	58
FY2019-20	37	108
FY2020-21	55	180
Total	**130**	**405**

Testosterone		
Children		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	130	330
FY2018-19	191	434
FY2019-20	248	615
FY2020-21	346	925
Total	**915**	**2,304**
Adults		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	63	174
FY2018-19	84	190
FY2019-20	87	210
FY2020-21	143	373
Total	**377**	**947**

Florida Medicaid

Children

Procedure Code	FY1718		FY1819		FY1920		FY2021	
	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count
19303-Mastectomy Simple Complete					2	4	3	6
19325-Breast Augmentation W/IMPLT								
53430-Reconstruction Of Urethra							1	1
54125-Amputation of penis; complete.							1	1
54520-Removal Of Testis	1	2					2	2
55180-Scrotoplasty; complicated.							1	1
55980-Sex Transformation F To M								
56805-Clitoroplasty							1	1
57110-Remove Vagina Wall Complete							1	1
57292-Construction of artificial vagina; with graft.							1	1
57335-Vaginoplasty							1	1
58571-Tlh W/T/O 250 G Or Less								
Total	**1**	**2**			**2**	**4**	**12**	**15**

Adults

Procedure Code	FY1718		FY1819		FY1920		FY2021	
	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count	Recipient Count	Procedure Code count
19303-Mastectomy Simple Complete	1	1	1	1	1	3	6	10
19325-Breast Augmentation W/IMPLT	1	1	1	2				
53430-Reconstruction Of Urethra							1	1
54125-Amputation of penis; complete.	1	1			1	1	1	1
54520-Removal Of Testis	1	1	1	1	5	7	2	3
55180-Scrotoplasty; complicated.								
55980-Sex Transformation F To M					1	1		
56805-Clitoroplasty	1	1					1	1
57110-Remove Vagina Wall Complete			1	1				
57292-Construction of artificial vagina; with graft.			1	1	2	2	1	1
57335-Vaginoplasty	1	1						
58571-Tlh W/T/O 250 G Or Less					1	1	1	2
Total	**6**	**6**	**5**	**6**	**11**	**15**	**13**	**19**

Florida Medicaid

H2019-Ther Behav Svc		
Children		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	143	1,024
FY2018-19	192	1,467
FY2019-20	183	1,440
FY2020-21	233	1,775
Total	**751**	**5,706**

Adults		
FY	**Recipient Count**	**No.of prescriptions**
FY2017-18	15	69
FY2018-19	20	128
FY2019-20	19	140
FY2020-21	33	320
Total	**87**	**657**

LOB	Complaint ID	Form Type	LOB State	Secondary Classification Disp	Classification Code	Classification Sub Code	Initial Received Date Time	Synopsis 1	Synopsis 4	Resolution
CW	MSHPFL-28349	FLMedicaid-Appeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	6/8/2022 7:55:00 AM	Request for SUPPRELIN LA Kit 50MG Kit	Given the additional information and the member's medical status, the original denial for a request for LA Kit 50 Milligrams (Inject 50 milligrams under the skin once every 365 days) is Overturned and approved as medically necessary. Approval One implant	Overturn
MMA	MSHPFL-28688	FLMedicaid-Appeals	MedicaidFL	Expedited Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	6/10/2022 3:07:00 PM	Request for SUPPRELIN LA Kit 50MG Kit	OVERTURN DENIAL AND APPROVE request for SUPPRELIN LA Kit 50MG Kit. Apply under the skin, one implant every 365 days	Overturn
MMA	MSHPFL-30587	FLMedicaid-Appeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Prior Auth Guidelines	6/29/2022 8:16:00 AM	Request for SUPPRELIN LA Kit 50MG Kit	OVERTURN the DENIAL AND APPROVE the request for Supprelin LA Kit 50 milligram Kit; Insert one implant under the skin every 12 months	Overturn
CMS XIX	MSHPFL-34152	FLMedicaid-RXAppeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	7/29/2022 7:37:00 AM	Request for SUPPRELIN LA Kit 50MG Kit	Supprelin LA Kit 50 milligrams 1 implant (50 milligrams of histrelin acetate) inserted under the skin in the inner aspect of the upper arm every 12 months	Overturn
MMA	MSHPFL-39712	FLMedicaid-RXAppeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	8/19/2022 6:58:00 AM	Request for SUPPRELIN LA Kit 50MG Kit	The appeal request for SUPPRELIN LA Kit 50MG is denied, due to Off-Label Drug Use for Dx: GENDER IDENTITY DISORDER UNSPECIFIED. Per Appeal study located on page 5 of 14 Initial Request Clinical Notes packet: This is not considered a Phase III clinical studies published in peer review journals to support the non-FDA approved use. EPSDT was taken into consideration for this review. Sunshine Health Off Label Use Prior Authorization Criteria was used in making this determination.	Uphold
MMA	MSHPFL-23357	FLMedicaid-Appeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	4/19/2022 1:04:00 PM	Requested Drug for ESTRADIOL Patch Weekly 0.1MG/24HR Patch	OVERTURN DENIAL. The member meets the Sunshine Health Plan Summary of Drug Limitations (SDL) limits Criteria for medical necessity. The request for Estradiol patch Weekly 0.1 milligrams per 24 hour patch, place two patches onto skin in male to female transgender person has supporting literature provided for the dose and diagnosis requested. Determination: Per Sunshine Health Plan Summary of Drug Limitations (SDL) limits Criteria the member meets criteria for approval. Approval directions: Estradiol patch Weekly 0.1 milligrams per 24 hour patch, place two patches onto skin in male to female transgender person Approval duration: 12 months	Overturn
CW	MSHPFL-6624	FLMedicaid-Appeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	9/8/2021 3:19:00 PM	Request for SUPPRELIN LA Kit 50MG Kit	Given this additional information and the member's medical status, the original denial for SUPPRELIN LA (Histrelin Acetate Implant Kit 50 MILLIGRAMS), Inject one implant (50 milligrams) is Overturned and approved as medically necessary. Approval is granted for Supprelin LA (Histrelin Acetate Implant Kit 50 MILLIGRAMS), Inject 1 Implant under the Skin Once For 1 Implant.	Overturn
MMA	MSHPFL-11588	FLMedicaid-Appeals	MedicaidFL	Pre-Service Appeal	Pharmacy Denial	RX - Does Not Meet Exception Guidelines	12/6/2021 12:07:00 PM	Request for SUPPRELIN LA Kit 50MG Kit	Advisor Review Completed by Medical Director Ernest Bertha, MD on 12/17/2021 at 10:09am. Request for treatment with SUPPRELIN LA Kit 50MG Kit is APPROVED as medically necessary. Approval is granted to inject 50 milligrams under the skin yearly... Approval is granted for a treatment duration of 1 year.	Overturn

Worksheet: Sheet1

AGENCY FOR HEALTH CARE ADMINISTRATION
After the Fact Request Form Under 35K

Requestor Name:	Devona Pickle	**Date:**	06/13/2022
Division/Bureau:	Medicaid/Medicaid Policy	**Vendor Name:**	Quentin Van Meter, MD, d/b/a Van Meter Pediatric Endocrinology
Phone:	850-412-4646	**Dollar Amount:**	Not to exceed $34,650.00 in combination with PR12154138
E-mail address:	Devona.Pickle@ahca.myflorida.com	**Dates of Service:**	4/15/22-6/30/22

Reason for Occurrence (brief explanation):
On April 20, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis of service coverage. While such requests are typically for a single service or good, this particular request called for a simultaneous analysis of three distinct services. Per the Agency's promulgated rule, the Agency must consider multiple factors, including recommendations or assessments by clinical or technical experts on the subject or field. Dr. Van Meter was approached regarding the Agency's consultation need and agreed to work with the Agency within those timeframes. Due to the enhanced scope of the project, the Agency sought subject matter expertise from outside of the Agency. **Dr. Van Meter completed his MFMP registration on May 24, 2022. However, he was not successful in updating his W-9 form until 6/13/22, despite multiple attempts. Dr. Van Meter worked with MFMP staff to resolve the issue. The consultant received confirmation of the acceptance of his W-9 on June 3, 2022. Because the consultant had not completed all components of the MFMP enrollment, we were unable to use the Agency's policy (4007) regarding urgent purchases.**

Why it was in the best interest of the State to Proceed:
Consultant services were used prior to issuance of the purchase requisition in order to ensure the time-sensitive analysis was comprehensive and complete by May 5, 2022.

Actions to be taken to Prevent Reoccurrence:
Consider whether the Agency's policy (4007) can be utilized to avoid an ATF request. We will continue to work with consultants to promptly enroll them in advance of receipt of services.

Division/Office Approval	
Supervisor's Name: (Required)	**Ann Dalton**
Signature: (Physical or email approval)	**Approved via email on 6/13/2022**

Pl. Trial Ex. 307

AHCA FORM 2100-0037, Revised: July 2014

AGENCY FOR HEALTH CARE ADMINISTRATION
After the Fact Request Form Under 35K

Purchasing Office Approval	
Approved: YES ☒ NO: ☐	
Comments:	
Purchasing Office Approver:	Ashley Balkcom 6/14/22

Invoice must be sent with ATF form. Supervisor approval is required, but may be in electronic form (email).

Submit all requests by email to: MFMP_Help@ahca.myflorida.com

AHCA FORM 2100-0037, Revised: July 2014

AGENCY FOR HEALTH CARE ADMINISTRATION
After the Fact Request Form Under 35K

Requestor Name:	Devona Pickle	**Date:**	05/26/2022
Division/Bureau:	Medicaid/Medicaid Policy	**Vendor Name:**	Andre Van Mol
Phone:	850-412-4646	**Dollar Amount:**	$6,125.00
E-mail address:	Devona.Pickle@ahca.myflorida.com	**Dates of Service:**	4/15/22-6/30/22

Reason for Occurrence (brief explanation):

On April 20, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis for service coverage. While such requests typically are for a single service or good, this particular request called for a simultaneous analysis of three distinct services. Per the Agency's promulgated rule, the Agency must consider multiple factors, including recommendations or assessments by clinical or technical experts on the subject or field. Due to the enhanced scope of the project, the Agency sought subject matter expertise from outside of the Agency. Due to the need to start work quickly, all of the purchase order elements were not available until May 6, 2022, which was after the start of work. Verification of the availability of funding and approval from executive leadership was obtained prior to any work being conducted for this project.

Why it was in the best interest of the State to Proceed:

Consultant services were used prior to issuance of the purchase requisition in order to ensure the time-sensitive analysis was comprehensive and complete by May 5, 2022.

Actions to be taken to Prevent Reoccurrence:

Consider whether the Agency's policy (4007) can be utilized to avoid an ATF request. We will continue to work with consultants to promptly enroll them in advance of receipt of services.

Division/Office Approval	
Supervisor's Name: (Required)	**Ann Dalton**
Signature: (Physical or email approval)	Approved via email

Purchasing Office Approval

Approved: YES ☒ NO: ☐

Comments:

Purchasing Office Approver: Ashley Balkcom 6/6/22

Invoice must be sent with ATF form. Supervisor approval is required, but may be in electronic form (email).

AHCA FORM 2100-0037, Revised: July 2014

Pl. Trial Ex. 307

AGENCY FOR HEALTH CARE ADMINISTRATION
After the Fact Request Form Under 35K

Submit all requests by email to: MFMP_Help@ahca.myflorida.com

AHCA FORM 2100-0037, Revised: July 2014

ATTORNEY WORK PRODUCT – CONFIDENTIAL
Pursuant to §119.071(1)(d)1., F.S.

This is a Rule Hearing on:

59A-1.010(7). F.A.C.; General Medicaid Policy

I. WELCOME/OPENING REMARKS

Good afternoon. This hearing is being conducted on Friday, July 8, 2022, from 3:00 p.m. to 5:00 p.m. in Tallahassee, Florida. The notice for this hearing was published in Volume 47, Number ___ of the Florida Administrative Register, on June ___, 2022.

This hearing is being conducted in accordance with section 120.54(2) of the Administrative Procedures Act. The purpose of the hearing is to allow the public to participate in the rulemaking process. Participants will be given an opportunity to provide comments on proposed changes to Rule 59G-1.050, Florida Administrative Code.

I am conducting the hearing for the Agency. My name is _____. Cole Giering. My address is Agency for Health Care Administration, 2727 Mahan Drive, M.S. #28A, Tallahassee, Florida 32308.

Other Agency personnel present are Jason Weida, Assistant Deputy Secretary for Medicaid Policy and Quality, _____ Matt Brackett, ~~with~~ _____, Program Consultant in the Agency's Bureau of Medicaid Policy, _____ ~~with~~ _____, and _____ Shena Grantham, Senior Attorney in the Agency's General Counsel's Office ~~with~~ _____. Also here on behalf of the Agency are the Agency's outside counsel—Mohammad Jazil and Gary Perko of the Holtzman Vogel law firm.

We're also pleased to have a panel of three experts in the field of general medicine, psychiatry, and endocrinology.

Dr. Andre Van Mol is a board-certified family physician. His graduated from the University of Southern California and the Medical College of Wisconsin. In addition to his

ATTORNEY WORK PRODUCT – CONFIDENTIAL
Pursuant to §119.071(1)(d)1., F.S.

clinical practice, Dr. Van Mol is a diplomate of the American Board of Family Practice.

Dr. Miriam Grossman, who is appearing remotely, is a board-certified child, adolescent, and adult psychiatrist. She graduated from Bryn Mawr College and New York University Medical School. She completed her residency in psychiatry, followed by a fellowship in child and adolescent psychiatry, through Cornell University.

And Dr. Quentin Van Meter is a pediatrician and pediatric endocrinologist. He graduated from The College of William and Mary and the Medical College of Virginia. He completed his pediatric endocrinology fellowship at The Johns Hopkins Hospital. In addition to his clinical practice, Dr. Van Meter is an adjunct associate professor of Pediatrics at Emory University School of Medicine and an Associate Clinical Professor of Pediatrics at Morehouse Schools of Medicine.

Drs. Van Mol, Grossman, and Van Meter are here to respond to substantive questions and comments about the proposed rule changes [redacted]

[redacted]

II. INTRODUCTORY STATEMENT

On April 20, 2022, the Florida Department of Health released guidance on the treatment of gender dysphoria for children and adolescents. [redacted] As a result, Secretary Simone Marstiller requested the Division of Medicaid to determine, under the process described in Florida Administrative Code Rule 59G-1035, ~~whether such~~what treatments are consistent with Generally Accepted Professional Medical Standards ("GAPMS") ~~generally accepted professional medical standards~~

Commented [TJ2]: Corrected the Secretarys name

and not experimental or investigational. The proposed rule changes are the result of that determination.

Specifically, the proposed changes would add subjection (7) to Rule 59G-1050—the Agency's General Medicaid Policy. The new subsection (7)(a) provides that the Florida Medicaid program does not cover the following services for the treatment of gender dysphoria: 1. Puberty blockers; 2. Hormones and hormone antagonists; 3. Sex reassignment surgeries; and 4. Any other procedures that alter primary or secondary sexual characteristics. The new subjection (7)(b) provides that, for the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

The determination [redacted] that the specifically listed [redacted] services [redacted] will not be covered ~~to~~ in the Florida Medicaid program [redacted] is based on extensive analyses conducted in accordance with Rule 59G-1.035. That rule [redacted] identifies factors [redacted] for determining ~~Generally Accepted Medical Procedures~~ GAPMS that are covered by the Florida Medicaid program. [redacted] Those factors include the following:

(a) Evidence-based clinical practice guidelines.

(b) Published reports and articles in the authoritative medical and scientific literature related to the health service (published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations).

(c) Effectiveness of the health service in improving the individual's prognosis or health outcomes.

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Pursuant to §119.071(1)(d)1., F.S.

(d) Utilization trends.

(e) Coverage policies by other creditable insurance payor sources.

(f) Recommendations or assessments by clinical or technical experts on the subject or field.

The GAPMS determination [redacted] is documented in a report that was posted on the Agency's website on June 2, 2022. As documented in that report, [redacted] the Florida Medicaid program [redacted] determined that the evidence supporting the effectiveness of the specific services listed above for the treatment of gender dysphoria [redacted] is low to very low quality and insufficient to demonstrative that such treatment conforms to the GAPMS ~~Generally Accepted Medical Procedure Standards~~ set forth in Rule 59G-1.035. Accordingly, ~~the Agency has~~ the Florida Medicaid program determined that the specific services listed above will not be covered for the treatment of [redacted] gender dysphoria [redacted] in the Florida Medicaid [redacted] program. [redacted]

Comment Procedure

Those of you who wish to speak are asked to state your name and the organization that you represent. We ask that comments be limited to the proposed rule language and the GAPMS

report underlying those changes. Due to the number of speakers, comments will be limited to ____ minutes per speaker.

[redacted]

In the interest of time, it is requested that speakers be mindful of their time, attempt to state your comments as succinctly as possible, and do not repeat the position of previous speakers. You may, however, for the record, state that you support the position of one or more previous speakers. In addition, given the number of interested parties with respect to this rule and to ensure that we do not run short on time, it would be the Agency's preference that, to the degree it is feasible to do so, each organization attempt to consolidate its comments regarding a given section to a single representative of that organization. We ask those of you who wish to comment to please submit your comments in writing by email directly to MedicaidRuleComment@ahca.myflorida.com before the end of the comment period, which I will announce at the end of this hearing.

III. CONDUCTING THE HEARING

Receive public comment. Moderator to field comments/ questions and, when within the prescribed topics of discussion, refer them to the appropriate panelist(s).

IV. CLOSING REMARKS

Thank you everyone for your participation in this hearing. We will accept written material or comments until **5:00 p.m., July 11, 2022**. Comments may be submitted by mail to _____, 2727 Mahan Drive, Mail Stop #31, Tallahassee, Florida, 32308, or by e-mail to MedicaidRuleComments@ahca.myflorida.com

There being no additional comments, this hearing is now closed.

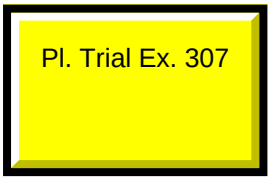
From: FL-Rules@dos.state.fl.us
Sent: Thursday, July 7, 2022 6:05 PM EDT
To: Cole.Giering@ahca.myflorida.com
Subject: One-time User Comment From FLRules.com

FLRules.com one-time comment:

Name: Ms.Mila Becker
Email: mbecker@endocrine.org
Title: 59G-1.050 General Medicaid
Comment: To Whom It May Concern:
The Endocrine Society strongly opposes the proposed rule, which would deny access to gender affirming care to the Florida Medicaid population. The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Many of our 18,000 members are recognized for their expertise in transgender medicine and research.

Our comments below are focused on responding to inaccurate and misleading statements about the Endocrine Society's clinical practice guidelines made in the report Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (GAPMS) developed by Florida Medicaid in June 2022, which is used to justify the proposed rule.

Quality of Endocrine Society Clinical Practice Guidelines on Endocrine Treatment of Gender Dysphoric/Gender Incongruent Persons and the GRADE System
The Institute of Medicine (IOM) (now known as the National Academy of Medicine) defined clinical practice guidelines as "recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." While guidelines are not standards of care that clinicians are legally bound to follow, they provide a framework for best practices, and deviations must be justified.
Endocrine Society guidelines are developed using a robust and rigorous process that adheres to the highest standards of trustworthiness and transparency as defined by the IOM. The Endocrine Society follows the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology to develop its recommendations. GRADE is the most accepted and internationally recognized standard for guideline development. Of the over 100 international groups that endorse GRADE, other prominent organizations using this methodology include the U.S. Agency for Healthcare Research and Quality, the U.S. Centers for Disease Control and Prevention, England's National Institute for Health and Care Excellence, and the World Health Organization. GRADE is a transparent framework for summarizing evidence and provides a systematic approach for making clinical practice recommendations.
GRADE begins with the formulation of clinical questions followed by a systematic review of the evidence that supports those questions. This evidence is used to develop and support the clinical recommendations that form the basis of the guideline. A certainty of evidence assessment is made for the overall body of evidence for a particular question on a scale from very low, low, moderate, to high. While some of the recommendations in the Endocrine Society's guideline are based on low or very low certainty evidence, strong recommendations can be made for low and very low certainty evidence in the GRADE system in some circumstances (Life threatening situation; uncertain benefit, certain harm; potential equivalence, one option clearly less risky or less costly, high certainty in similar benefits, one option potentially more risky or costly; potential catastrophic harm.) Additionally, the GRADE methodology does not account only for the certainty of the evidence when developing recommendations. Systematic reviews of the effects of an intervention provide essential, but not sufficient information for making informed decisions. There are other factors that GRADE methodology requires guideline authors to account for including, most importantly, patient values and preferences, in making trade-offs between alternative courses of action.
Additionally, Endocrine Society guidelines are not developed in a vacuum. Guidelines take an average of 2-3 years to be developed through a multi-step drafting, comment, review, and approval process. This includes a public comment period and expert review period, and all comments are addressed by the guideline development panel prior to publication. Expert reviewers are subject to the same conflict of interest rules as panel members. There is ample opportunity for feedback and debate through this years-long development process.



Consequently, the Endocrine Society's guidelines represent a high-quality resource to be used for patient care based on medical evidence, author expertise, rigorous scientific review, and a transparent process. In contrast, GAPMS did not include endocrinologists with expertise in transgender medicine, misunderstands the use of the GRADE methodology and the notion of standard of care, and makes sweeping statements against gender affirming medical care that are not supported by evidence or references provided. Most disturbing, GAPMS does not acknowledge the data showing harm reduction and improvements in behavioral health issues, such as depression and anxiety, with gender affirming care.

Sufficiency of Evidence and Bar for Gender Affirming Care

The Endocrine Society and other medical and mental health organizations representing professionals who treat gender dysphoria/gender incongruence firmly believe there is sufficient evidence to support gender affirming care and to support that harm can occur if these people are not treated. The statement in GAPMS that "low quality" studies provide insufficient evidence for gender affirming care demonstrates a failure to understand medical literature. The medical literature terminology is appropriately conservative. But "low-quality" studies are typical for much of medical care and much better than "expert opinion," also common for medical care.

The Endocrine Society believes Florida is imposing a bar for care that is too high, will result in harm to people with gender dysphoria/incongruence, and is not used for other patients. GAPMS suggests that because puberty blockers are used off-label they are experimental and not safe. The fact is many treatments used in medicine are used off-label. That just means that medication is used for a purpose other than that for which the pharmaceutical company did the paperwork. Such prescribing is common. That is part of the reason states license physicians, to make those prescribing decisions. FDA approval and randomized controlled trials are simply too stringent. Most medical care occurs appropriately without those in place.

Scientific Evidence Indicates the Effectiveness of Treating Gender Dysphoria According to the Guidelines

The results of multiple studies indicate that adolescents suffering from gender dysphoria who receive medical interventions as part of their gender-affirming care experience improvements in their overall well-being. Eight studies have been published that investigated the use of puberty blockers in the care of adolescents suffering from gender dysphoria and six studies have been published that investigated the use of hormone therapy to treat adolescents suffering from gender dysphoria. These studies find positive mental health outcomes for those adolescents who received puberty blockers or hormone therapy, including statistically significant reductions in anxiety, depression, and suicidal ideation.

For example, a 2020 study analyzed survey data from 89 transgender adults who had access to puberty blockers while adolescents and from more than 3,400 transgender adults who did not. The study found that those who received puberty blocking hormone treatment had lower likelihood of lifetime suicidal ideation than those who wanted puberty blocking treatment but did not receive it, even after adjusting for demographic variables and level of family support. Approximately nine in ten transgender adults who wanted puberty blocking treatment but did not receive it reported lifetime suicidal ideation. Additionally, a longitudinal study of nearly 50 transgender adolescents found that suicidality was decreased by a statistically significant degree after receiving gender-affirming hormone treatment. As another example, a prospective two-year follow-up study of adolescents with gender dysphoria published in 2011 found that treatment with puberty blockers was associated with decreased depression and improved overall functioning. A six-year follow-up study of 55 individuals from the 2011 study found that subsequent treatment with hormone therapy followed by surgery in adulthood was associated with a statistically significant decrease in depression and anxiety. "Remarkably, this study demonstrated that these transgender adolescents and young adults had a sense of well-being that was equivalent or superior to that seen in age matched controls from the general population." As scientists and researchers, the Endocrine Society always welcomes more research, including on this crucial topic. However, the available data indicate that the gender-affirming treatments that would be denied by the proposed rule are effective for the treatment of gender dysphoria. For these reasons, the use of the gender-affirming medical interventions specified in the Endocrine Society's guidelines is supported by all mainstream pediatric organizations, representing thousands of physicians across multiple disciplines.

Statements in GAPMS are Factually Inaccurate and Ignore the Recommendations of the Medical Community

GAPMS asserts that most adolescents who experience gender dysphoria will later overcome it by confirming to their natal sex. This assertion lacks scientific support. While some prepubertal children who experience gender dysphoria may go on to identify with their sex assigned at birth by the time they reach puberty, there are no studies to support the proposition that adolescents with gender dysphoria will come to identify with their sex assigned at birth, whether they receive treatment or not. On the contrary, "[l]ongitudinal studies have indicated that the emergence or

worsening of gender dysphoria with pubertal onset is associated with a very high likelihood of being a transgender adult."
Further, GAPMS relies upon controversial research not recognized in the mainstream transgender medicine community. For example, it refers to a paper by Lisa Littman on Rapid Onset Gender Dysphoria (ROGD) – a condition that does not exist -- to justify not supporting gender affirming medical care for adolescents with gender dysphoria without noting the methodological concerns that have been raised regarding this paper, including the fact that only parents (recruited from anti-transgender websites) and none of the youth with gender dysphoria participated in the study, and that parents were not recruited from websites supportive of transgender youth. These methodological concerns prompted publication of a correction by the original author.

The Proposed Rule Would Irreparably Harm Many Adolescents with Gender Dysphoria by Denying Access to the Treatment They Need
The proposed rule would deny Medicaid beneficiaries with gender dysphoria access to medical interventions that alleviate suffering, are grounded in science, and are endorsed by the medical community. The medical treatments prohibited by the proposed rule can be a crucial part of treatment for people with gender dysphoria and necessary to preserve their health. As discussed above, research shows that people with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is associated with reductions in the rate of suicide attempts and significant improvement in quality of life. In light of this evidence supporting the connection between lack of access to gender-affirming care and lifetime suicide risk, banning such care can put patients' lives at risk.
The Endocrine Society is eager to work with Florida to address these concerns and would be happy to connect Florida Medicaid with our transgender medicine experts. If we can be of assistance or provide any additional information, please contact our Chief Policy Officer at mbecker@endocrine.org.

Sincerely,

Ursula Kaiser, MD
President, Endocrine Society

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July 8, 2022

VIA E-MAIL AND WEBSITE

Simone Marstiller, Secretary
Tom Wallace, Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308
MedicaidRuleComments@ahca.myflorida.com

Re: Rule No. 59G-1.050: General Medicaid Policy

Dear Secretary Marstiller and Deputy Secretary Wallace:

We are writing to submit a public comment on a proposed amendment to Section 59G-1.050 of the Florida Administrative Code (the "Proposed Rule"), which, if adopted, would deny medical treatment to transgender individuals.[1] The Proposed Rule would apply to Medicaid members of any age and would deny coverage for puberty blockers, hormones, "sex reassignment surgeries," and "any other procedures that alter primary or secondary sexual characteristics."[2]

We are a group of seven scientists and a law professor, and we are deeply dismayed by the content of the Proposed Rule, which will deny long-established, effective, and evidence-based medical care to thousands of Florida Medicaid patients.[3] We are also distressed as scientists and stewards of public health by the shoddy quality of the purported scientific report offered to justify the Proposed Rule. The report, issued by the Florida Agency for Health Care Administration ("AHCA") on June 2, 2022 (hereinafter, "June 2 Report"), disregards well-established clinical practice guidelines and scientific research showing that standard medical treatments for gender dysphoria are "consistent with generally accepted professional medical standards" and are not "experimental or investigational."[4]

As discussed in depth below, we strongly oppose the adoption of the Proposed Rule. The Proposed Rule would violate the sex discrimination protections provided by the U.S. and Florida Constitutions and the federal statute that governs Medicaid by discriminating against transgender people on the basis of their sex, transgender status, and gender identity.[5] We are confident that other comments will focus in depth on the legal authorities that pre-empt the Proposed Rule.

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[1] 48 Fl. Admin. Reg. 2461 (June 17, 2022). The Notice of Development of Rulemaking was published in 48 Fl. Admin. Reg. 2270 (June 3, 2022) without any specification of the subject of the rulemaking.
[2] The Proposed Rule would add new subsection (7) to Fl. A dmin. Code Section 59G-1.050. See 48 Fl. Admin. Reg. 2461 (June 17, 2022).
[3] Our comments reflect our views and not those of the University of Alabama, the University of Texas, or Yale University.
[4] Division of Florida Medicaid, Agency for Health Care Adm inistration, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, June 2022, at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf ("June 2 Report").
[5] See Bostock v. Clayton County, 590 U.S. __ (2020); Kadel v. Folwell, M.D. N.C., Mem. Op. 6-10-22 (applying Bostock to public health plan coverage); 42 U.S.C. 18116 (requiring nondiscrimination in Medicaid plans).

Pl. Trial Ex. 307

Our comments focus instead on the absence of any persuasive scientific or medical justification for the Proposed Rule. The June 2 Report purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unsound from a scientific perspective. The June 2 Report disregards established scientific knowledge, ignores longstanding clinical practice recommendations developed by authoritative bodies of medical experts, and unaccountably dismisses the medical recommendations of more than 20 medical societies.

As scientists, we are alarmed that Florida's health care agency has adopted a purportedly scientific report that so blatantly violates the basic tenets of scientific inquiry. The report contains glaring errors regarding science, statistical methods, and medicine. Ignoring established science, the report instead relies on biased and discredited sources, stereotyping, and purported "expert" reports that carry no scientific weight.

These fundamental flaws thoroughly discredit the conclusions of the June 2 Report, with two legal consequences. First, the complete absence of scientific foundation for the Proposed Rule renders it an arbitrary and capricious use of rulemaking power. Second, the Florida AHCA cannot characterize the Proposed Rule as a valid interpretation of the existing Florida regulations on generally accepted professional medical standards, because the June 2 Report fails to satisfy Florida's own regulatory requirements for scientific review.[6]

The seven scientists in our group hold academic appointments at the University of Alabama, the University of Texas Southwestern, and Yale University. (The law professor is a tenured professor at the Yale Law School.) We include three Ph.D child and adolescent psychologists and four M.D. physicians with specialties in pediatric endocrinology, child and adolescent psychiatry, and adolescent medicine. All seven are also clinicians who treat transgender youth on a daily basis. Among us, we have accumulated more than 57 years of clinical practice and have treated more than 2,100 transgender youth. We received no funding for our work and have no conflicts of interest to declare.

We are writing to comment on the Proposed Rule because we are concerned that it will harm transgender people in Florida and set a misleading and dangerous national precedent. We are committed to the integrity of science and law, and we strongly oppose legal actions that, like the Proposed Rule and the June 2 Report, claim the authority of science but provide only biased and misleading information. Youth, families, and medical providers in Florida deserve a higher standard of protection and service from their government.

In this comment letter, we focus on the science governing the treatment of gender dysphoria. Our observations are relevant to the treatment of both youth and adults. For example, we show that the June 2 Report falsely claims that the evidence for medical treatment for gender dysphoria does not meet generally accepted professional medical standards and is experimental. We also show that the June 2 report relies on purported "expert" reports that appear to be highly biased and with undisclosed conflicts of interest. To keep our comments focused and manageable in length, the one issue that we do not address is the science of genital surgery used to treat gender dysphoria, which is typically not performed before the age of majority. We are confident that the

[6] See Fl. Admin. Code Section 59G-1.035(1) and (4).

evidence base for surgical procedures is sound, and we are confident that others will address the June 2 Report's erroneous claims regarding surgery.

Throughout our comments, we refer to our companion report, *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, which is attached as Appendix A. The report goes into greater detail on many of the points we raise here.

Background

The AHCA appears to have taken a belt-and-suspenders approach to denying Medicaid coverage for standard medical treatment for gender dysphoria: the agency appears to be pursuing two legal strategies simultaneously. The June 2 Report reflects the first strategy, which frames the denial of care as an interpretation of the existing Florida Medicaid coverage regulations.[7] The Florida Medicaid program covers only health services that are "medically necessary" and excludes services that do not meet "generally accepted professional medical standards or are "experimental or investigational." The existing regulations permit the AHCA to determine when health services are consistent with generally accepted professional medical standards (GAPMS).

Specifically, the existing regulations authorize the Florida Deputy Secretary for Medicaid to make a final coverage determination; however, the Deputy Secretary does not have unfettered interpretive authority. The Florida Administrative Code sets out a detailed process, which requires the AHCA to prepare a report that considers scientific evidence including "evidence-based clinical practice guidelines" and "published reports and articles in the authoritative medical and scientific literature related to the health service (published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations)."[8] The June 2 Report purports to be such a report. It is titled a "Generally Accepted Professional Medical Standards Determination" and concludes that standard medical treatments for gender dysphoria "do not conform to GAPMS and are experimental and investigational."[9]

The AHCA has also pursued, simultaneously, a second legal strategy by publishing the Proposed Rule on June 17. The Proposed Rule makes no reference to the June 2 Report and contains no independent justification for the rule. The Proposed Rule would add a new subsection to Section 59G-1.050 of the Florida Administrative Code, Section (7), which would deny Medicaid coverage in Florida for medical care for gender dysphoria. The Proposed Rule would apply to Medicaid members of any age and would deny coverage for puberty blockers, hormones, "sex reassignment surgeries," and "any other procedures that alter primary or secondary sexual characteristics.[10] According to the Notice of Proposed Rule published in the Florida Administrative Register, a public hearing will be held on July 8, 2022, and public comments on the Proposed Rule may be submitted through that date.[11]

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[7] See June 2 Report, p. 2 (noting that the Secretary of the Florida Agency for Health Care Administration requested the report from the Florida Division of Medicaid pursuant to Section 59G1.035 of the Florida Administrative Code,
[8] Fl. Admin. Code Section 59G-1.035(4).
[9] The report makes specific reference to these rules.June 2 Report, p. 2.
[10] 48 Fl. Admin. Reg. 2461 (June 17, 2022).
[11] See id. and the instructions at https://www.flrules.org/Gateway/View_notice.asp?id=25979915

Analysis

In our comments below, we show that there is no scientific justification for the Proposed Rule and no scientific justification for the conclusions drawn in the June 2 Report.

1. The Proposed Rule would deny Florida Medicaid coverage for standard medical care for gender dysphoria, which is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.

The conclusion of the June 2 report – that medical treatments for gender dysphoria "do not conform to [generally accepted professional medical standards] and are experimental and investigational" -- is demonstrably false.

Medical care for the treatment of gender dysphoria, which for youth under the age of majority can include gonadotropin releasing hormone agonists ("GnRHa" or puberty blockers) and hormone therapy, has been vetted and approved by international bodies of experts based on the scientific evidence. Two authoritative bodies of scientists, the World Professional Association for Transgender Health (WPATH) and The Endocrine Society, have published extensive clinical practice guidelines for treating gender dysphoria.[13] These clinical guidelines are based on rigorous, structured processes. Each involves the work of a committee of scientific experts and peer review by additional experts. The guidelines are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments.

These longstanding clinical practice guidelines have been used by clinicians for decades. WPATH issued its initial guidelines in 1979 and updated them in 1980, 1981, 1990, 1998, 2001, and 2012. The eighth version remains in process, and it incorporates systematic literature reviews and ample opportunities for peer review and revision.[14] The original Endocrine Society guidelines were published in 2009 and updated in 2017.[15]

Reflecting this scientific and medical consensus, medical care for gender dysphoria has been confirmed as standard care by every relevant medical organization in the United States, including the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry.[16] In 2022, these organizations united

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June 2 Report, p. 2.

[13] See Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Professional Association for Transgender Health (7th version, 2012), at https://www.wpath.org/publications/soc ("WPATH (2012)"); Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102(11) J. Clin. Endocrinol. Metab. 3869-3903 (2017) ("Endocrine Society (2017)").

[14] See World Professional Association for Transgender Health (WPATH), Methodology for the Development of Standards of Care 8 (Soc 8), at https://www.wpath.org/soc8/Methodology

[15] Endocrine Society (2017), supra note 13.

[16] Jason Rafferty, Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142(4) Pediatrics E20182162 (2018); American Psychological Association, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70(9) American Psychologist 832-64 (2015); Stewart L. Adelson, Practice Parameter on

with the American Medical Association, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and other groups to file an amicus brief representing a total of 20 major medical societies. The brief reaffirms that puberty blockers and hormone treatments for gender dysphoria are standard medical care and opposes legal measures that would limit patient access to this standard care.[17]

The weight and volume of these endorsements, across diverse medical specialties, sharply contradicts the June 2 Report's conclusion and undermines any purported scientific justification for the Proposed Regulation.

As further evidence, it is critical to note that the medications used to treat gender dysphoria are used commonly and safely in cisgender patients. Puberty blockers are the main treatment for central precocious puberty. Estrogen is prescribed for patients of all ages to manage fertility and reduce heavy menstrual bleeding (to give just two examples of its many uses). Testosterone is prescribed to address hypogonadism, and spironolactone (androgen blockade) is used to treat hirsutism and acne.

The Florida Medicaid program covers all these uses without question. The program authorizes physicians to tailor treatments to cisgender patients' needs and trusts patients (and, in the case of children, their parents) to make informed decisions. The Proposed Rule would deny coverage only for gender dysphoria, discriminating against transgender patients.

2. The June 2 Report appears to be a scientific report, but its veneer hides a flawed analysis that ignores the scientific evidence and relies on pseudo-science that does not meet Florida's own standards for review. The June 2 Report provides no scientific foundation for the Proposed Rule and fails to meet Florida's own regulatory requirements for Medicaid coverage determinations.

The Florida report dismisses or ignores the WPATH and Endocrine Society clinical practice guidelines and the science that underlies them and instead relies on five attached documents that, the report claims, constitute "clinical and technical expert assessments."[18]

Despite their billing as "expert" reports, the attachments to the June 2 report are unpublished, non-peer-reviewed documents written by authors with questionable claims to expertise and with red flags for undisclosed author bias. These documents should be given no weight in a serious scientific process.

The June 2 Report purports to be a coverage determination pursuant to Fl. Admin. Code Section 59G-1.035, but its reliance on these five documents constitutes a gross violation of the process set out in that regulation. The regulation requires that the AHCA consult actual scientific evidence, including "evidence-based clinical practice guidelines" and "*published* reports and

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Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, 51(9) J. Am. Acad. Child & Adolescent Psychiatry, 957 -974 (2012).

[17] Brief of Amicus Curiae American Academy of Pediatrics and Additi onal National and State Medical and Mental Health Organizations in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction, Eknes-Tucker v. Ivey (later redesignated Eknes-Tucker v. Abbott), May 5, 2022, at https://www.aamc.org/media/60556/download

[18] June 2 Report, p. 2.

articles in the authoritative medical and scientific literature related to the health service (published in *peer-reviewed* scientific literature generally recognized by the relevant medical community or practitioner specialty associations)."[19]

The June 2 Report reads like a roadmap for how to violate these rules. The report disregards the evidence-based clinical practice guidelines published by WPATH and The Endocrine Society and relies entirely on the five attachments, which are not published, are not peer-reviewed, and are written by inexpert and biased authors.

A. The purported "expert" documents attached to the June 2 Report are unpublished and not peer-reviewed, and they are written by authors whose expertise has been successfully challenged in legal proceedings and whose professional histories raise red flags for bias.

None of the documents attached to the June 2 Report meet standard criteria for expert scientific investigations, because none is published or peer reviewed. Publication and peer review are fundamental to science, as they ensure that a scientist's data and conclusions are open to scrutiny from scientific experts.

Florida's own standards for the determination of medical necessity recognize this point when they state that determinations of Medicaid coverage must consult "*published* reports and articles in the authoritative medical and scientific literature related to the health service (*published in peer-reviewed scientific literature* generally recognized by the relevant medical community or practitioner specialty associations)."[20] It is thus both unscientific and a violation of the regulations for the June 2 Report to rely on unpublished documents as its principal evidence base.

Further, the attachments raise red flags for author bias. The June 2 Report does not disclose how these "experts" were identified or by what criteria their expertise was assessed. The opacity of the Florida AHCA process for identifying experts is particularly troubling because at least four of the five experts have strong indications of bias. Further, the qualifications and credibility of two of the experts have been successfully challenged in litigation.[21] The endorsement of these individuals as Florida's banner "experts" raises the appearance of bias – that the AHCA sought a pre-ordained outcome, not a true scientific perspective.

Adding to these red flags for bias, none of the authors of the attachments provide a statement of funding and conflicts of interest. This omission violates a strong norm in scientific writing, which requires authors to declare any professional or financial arrangements that could call into question their independence of judgment.[22] That strong norm also requires authors to disclose

[19] Fl. Admin. Code Section 59G-1.035(4).
[20] Fl. Admin. Code Section 59G-1.035(4).
[21] See Stephen Caruso, A Texas Judge Ruled That This Doctor Was Not an Expert, Pennsylvania Capital-Star, Sept. 15, 2020 (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed).
[22] For example, the conflict of interest rules for JAMA, one of the premier medical journals in the United States and the world state that "[a]uthors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript) including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers' bureaus, stock ownership or options, expert testimony, royalties, donation of

whether projects have been funded and if so, by whom and whether the authors have engaged in expert testimony. Without these statements, the Florida AHCA and the public cannot detect biases that could affect the integrity of these written products.

These are more than theoretical concerns: *four of the attachments have notable indicators of conflicts of interest and bias*. (Note that these are the only four we examined in detail, and so we do not imply that the other one is free from such bias.)

The author of the document provided as Attachment E is Quentin van Meter, whose history indicates bias and lack of expertise. Although the AHCA presents van Meter as an expert in medical treatment for gender dysphoria, at least one court barred him from providing expert testimony on the issue.[23] Van Meter is the president of the American College of Pediatricians (the "ACP"), which presents itself as a scientific group (and might be confused, by a non-expert, with the authoritative American Academy of Pediatrics). The ACP is, in fact, a political group that opposes same-sex marriage,[24] supports mental health providers practicing conversion therapy,[25] and describes gender dysphoria as "confusion."[26] Troublingly, the van Meter attachment, proffered by the AHCA as a scientific report, contains several passages of uncredited, verbatim language that appears in a "position statement" published by the ACP.[27] The van Meter attachment appears to be a re-use of paid testimony rather than an original product.[28]

James Cantor's document, presented as Attachment D to the June 2 Report, also faces serious questions about bias and lack of expertise. In a 2022 case, a federal court took a skeptical view of Cantor's purported expertise, giving his testimony little weight because Cantor has "no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria.[29] Cantor's document is nearly identical to what

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medical equipment, or patents planned, pending, or issued." JAMA Network, Instructions for Authors, visited June 22, 2022, at https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecConflictsofInterestandFinancialDisclosures

[23] Caruso, supra note 21.

[24] Den Trumbull, Defending Traditional Marriage, American College of Pediatricians (2013), https://acpeds.org/position-statements/defending-traditional-marriage. See Jack Turban, The American College of Pediatricians is an Anti-LGBTQ Group, Psychology Today, May 8, 2017.

[25] Christopher Rosik and Michelle Cretella, Psychotherapy for Unwanted Homosexual Attraction Among Youth, American College of Pediatricians (2 016), https://acpeds.org/position-statements/psychotherapy-for-unwanted-homosexual-attraction-among-youth.

[26] Michelle Cretella, Gender Dysphoria in Children, American College of Pediatricians (2018), https://acpeds.org/position-statements/gender-dysphoria-in-children (site visited June 22, 2022). The author of the ACP position paper is Michelle Cretella, who was publicly rebuked by the Society for Adolescent Health and Medicine, the leading society for adolescent medicine in the United States, for "pushing political and ideological agendas not based on science and facts." https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-(2).aspx

[27] The similarity was shown by a Word comparison of the van Meter report provided as Attachment E to the June 2 Report with a "position statement" published on the ACP website, with authorship credit given on the website to Michelle Cretella. See Michell e Cretella, Gender Dysphoria in Children, supra note 26.

[28] The van Meter document attached to the June 2 Report is substantially identical to his expert declaration in Adams v. School Board of St. Johns County, Florida. https://files.eqcf.org/wp-content/uploads/2017/12/41-D-AMENDED-Notice-Documents-iso-Response-to-PI.pdf.

[29] Opinion and Order, Eknes-Tucker v. Marshall, 2:22-CV-184-LCB, M.D. Alabama, May 13, 2022.

appears to be paid testimony in another case, where Cantor's declaration was used to support legislation barring transgender athletes from sports teams,[30] Troublingly, Cantor's appearance in that case seems to have been funded by the Alliance Defending Freedom ("ADF"), [31] a religious and political organization that opposes legal protections for transgender people and same-sex marriage[32] and defends the criminalization of gay sex.[33]

Romina Brignardello-Petersen is one of two authors of the document provided as Attachment C to the June 2 Report. Although Brignardello-Petersen claims to have no research interests in medical care for transgender youth,[34] she has conducted research for the Society for Evidence-Based Gender Medicine ("SEGM").[35] Although SEGM claims to be an international medical society, it is, in fact, an advocacy group that opposes standard medical care for gender dysphoria. The SEGM has no publications or conferences and seems to consist solely of a website. The group appears to be run by a small group of people with limited or no scientific credentials and the website presents a cherry-picked collection of studies and narrative content that is full of scientific errors.[36]

Patrick Lappert, whose document is attached to the June 2 Report as Attachment F, has been disqualified as an expert in a recent federal court decision in North Carolina. [37] The judge found that the evidence "calls Lappert's bias and reliability into serious question" and noted that Lappert has worked closely with ADF and has actively lobbied for legal bans on medical care for

[30] The case is BPJ v. West Virginia State Board of Education, and the Alliance Defending Freedom takes credit for it here: https://adfmedia.org/case/bpj-v-west-virginia-state-board-education. Cantor's declaration appears here: https://adfmedialegalfiles.blob.core.windows.net/files/BPJ_CantorDeclaration.pdf

[31] The ADF seems to take credit for the case in this press conference notice:https://adfmedia.org/case/bpj-v-west-virginia-state-board-education

[32] Marriage is the Future, American College of Pediatricians, https://adflegal.org/issues/marriage/overview(site visited July 2, 2022. Content on the page includes this statement:"Marriage is about equality and diversity. It's about joining the two equally important and diverse halves of humanity represented in men and women."

[33] Southern Poverty Law Center, Dangerous Liaisons, July 10, 2013, https://www.splcenter.org/20130709/dangerous-liaisons [visited July 2, 2022].

[34] Like the van Meter and Cantor attachments, the BPW document provides no express statement of conflicts of interest. The BPW document does offer a statement of "credentials and expertise," in which she declares that "her research interests are not in this area," meaning apparently research on medical care for gender dysphoria. BPW Document, p. 1.

[35] BPW document, p. 1. For one example of the purported research that Brignardello -Petersen apparently assisted in, see Alison Clayton et al., Commentary: the Signal and the Noise– Questioning the Benefits of Puberty Blockers for Youth with Gender Dysphoria – A Commentary on Rew et al. (2021), Child and Adolescent Mental Health, Dec. 22, 2021, at https://acamh.onlinelibrary.wiley.com/doi/10.1111/camh.12533 In the "Acknowledgements" section, the authors state, "We would also like to thank the Society for Evidence -based Gender Medicine (SEGM) for providing access to several experts who helped shape this commentary and ensure its accuracy. Specifically, we would like to thank Dr. Romina Brignardello Petersen [sic] for contributing her methodological expertise."

[36] Susan Boulware et al., Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims (April 28, 2022), at 28-29 (Appendix A) available at https://medicine.yale.edu/childstudy/policy-and-social-innovation/lgbtq-youth/.

[37] Kadel v. Folwell, 1:19CV272, M.D. N.C. June 10, 2022. The judge ruled that Lappert was not qualified to "render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments." Lappert was also disqualified from opining on "the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria." Id.

transgender youth.[38] The judge gave no weight to Lappert's testimony about informed consent, finding that it was unsupported by scientific evidence.[39] The judge also found that "Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has "never been generally accepted by the relevant scientific community."[40]

B. The linchpin of the June 2 Report is the analysis by Brignardello-Petersen and Wiercioch (the "BPW document"), provided as Attachment C, which purports to be a comprehensive review of the scientific literature but, in fact, is extremely narrow in scope and so flawed in its analysis that it merits no scientific weight at all.

The BPW document, like the other attachments to the June 2 Report, is an unpublished, non-peer-reviewed document. It is written by inexpert authors who construct an arbitrarily truncated sample and adopt a method that violates scientific guidelines and produces a biased result. The authors describe their findings in deceptive language and jargon predictably mislead the reader. Our review shows that *nothing in the BPW document calls into question the scientific foundations of the WPATH and the Endocrine Society clinical practice guidelines.*

The BPW document seems scientific on its face, because it uses technical jargon and includes numerous tables and charts. But a closer examination shows that it violates established standards for medical research and shows signs of being engineered to produce a pre-ordained and inaccurate result.

The bottom line is that, contrary to the BPW document's claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria.

(1) The BPW document lacks scientific credibility due to the authors' lack of relevant qualifications and their ties to an activist group.

The BPW document purports to be a systematic review of the scientific literature on medical treatment for gender dysphoria, but it is full of errors and omissions, resulting in a biased and misleading result. Here, we describe just three of the notable defects that undercut entirely the document's claim to objectivity and sound method. We provide additional detail on these errors in the Appendix to these comments.

First, *neither of the BPW authors are experts* in medical care for gender dysphoria, either as researchers or clinicians. One author (Brignardello-Petersen) has not previously studied the subject, except in her work for the ideological organization SEGM.org, noted just above. Her only clinical experience appears to be in dentistry.[41] The other author (Wiercioch) is a junior researcher (a postdoctoral fellow) with no prior research or clinical experience in this field.[42]

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[38] Id.
[39] Id., pp. 29-30.
[40] Id., p. 31.
[41] Romina Brignardello bio, at https://experts.mcmaster.ca/display/brignarr[visited July 2, 2022]
[42] Google Scholar, Wojtek Wiercioch, visited June 22, 2022, https://scholar.google.com/citations?user=vdi3r_AAAAAJ&hl=en

The authors' lack of interest and experience renders the BPW work inexpert rather than objective, and it violates the National Academy of Medicine standards for systematic reviews.[43] By analogy, one would not rely on, say, two dermatologists to conduct a review of the scientific literature on neurosurgery and to make recommendations for clinical practice.

Second, not only is the study not formally peer-reviewed, the BPW authors violate scientific norms and standards by *failing to engage at all with their peers or with actual experts* in the subject matter.[44] The BPW authors appear not to have published their protocol in advance or otherwise to have submitted their protocol for peer review.

Third, the BPW document raises red flags for opinion bias. Buried in the methodology pages of the BPW document is the fact that the authors include the fringe website SEGM.org.[45] As noted above, the group's website posts are not peer-reviewed or published, and its cherry-picked content is assembled by activists and is often full of errors.[46] Troublingly, this is the group to which one of the authors, Brignardello-Petersen, has ties, as noted above.

(2) The BPW document violates scientific standards for evaluating medical evidence. The picture that emerges is of a rushed and inexpert report with indications of bias.

The BPW document has a patina of scientific expertise. It invokes the respected GRADE standards for rating the quality of studies, and it occupies many pages with tables and technical specifications. When a reader looks past the jargon, however, the BPW authors adopt a method that violates scientific standards and appears to be jury-rigged to reach a foregone conclusion. The authors convey their conclusions in misleading language. *Contrary to the BPW authors' claims, their study does not call into question the scientific and clinical importance of the established science that supports medical care for gender dysphoria.*

The BPW analysis incorporates numerous decisions that bias the results, and the authors describe their findings in grossly misleading terms. To begin, the BPW document reviewed only a small sample of the relevant scientific literature. In the introduction, the BPW authors initially claim to have reviewed 61 systematic reviews of medical treatment for gender dysphoria.[47] But buried in

[43] Committee on Standards for Systematic Reviews of Comparati ve Effectiveness Research, Institute of Medicine, Finding What Works in Health Care: Standards for Systematic Reviews, National Academies (Jill Eden et al., eds 2011), p. 48 (Standard 2.1.1 states that teams for systematic reviews should include expertise in pertinent clinical content areas). Background: The Institute of Medicine, now called the National Academy of Medicine, is one of three branches of the National Academies of Science, Engineering, and Medicine. The National Academy of Science dates to 1963 and was established by Congress; the Institute of Medicine was established as a separate entity in 1970 and serves as the nation's leading authority on scientific research and knowledge. National Academy of Medicine, About the National Academy of Medicine, website visited June 22, 2022, https://nam.edu/about-the-nam/ The standards for systematic reviews were published in 2011, responding to a Congressional request to set benchmarks for high-quality systematic reviews that could reliably guide physicians and health-care providers in making informed, scientific judgments about health care.
[44] For additional detail, see the Appendix.
[45] BPW document, Methods section, p. 2.
[46] See Boulware et al., supra note 36, pp. 28-29 (Appendix A).
[47] BPW document, Introduction Section, p. 2.

the middle of the document is the admission that the analysis is based on a sample of 27 systematic reviews, not 61 as claimed.[48]

Troublingly, the authors also embed in the middle of their technical document an unjustified decision to limit their analysis to studies published from 2020 to the present. The authors disclose that they "prioritized" studies from the last 30 months (two full years plus four months in 2022), but they do not defend that priority. The reader is left to wonder whether this truncation served only to help the authors produce their analysis in a very short time frame.

Further, the BPW authors mechanically apply a series of rating systems (AMSTAR and GRADE) for assessing the quality of scientific evidence, but their use violates key principles for using these systems. Based on this mechanical review of truncated sources, the BPW analysis reaches the conclusion that there is little or no evidence for the benefits of medical care for gender dysphoria.[49]

But the BPW analysis is deceptive, because it dismisses nearly all existing studies of medical treatment for gender dysphoria as "low quality," without explaining that this is a highly technical term and not a natural-language condemnation of the studies. By contrast, the GRADE system, which the authors purport to use, is quite clear about its quality rating systems and its limitations.[50] We provide additional detail on the authors' misuse and deceptive statements in the Appendix.

The key point is that "low quality" in this context is a technical term and not a condemnation of the evidence, because "low quality" studies regularly guide important aspects of clinical practice. Indeed, the GRADE system, which the BPW document claims to use, specifically notes that GRADE should *not* be used to dismiss observational studies or to give absolute priority to RCTs:

> Although higher quality evidence is more likely to be associated with strong recommendations than lower quality evidence, a particular level of quality does not imply a particular strength of recommendation. *Sometimes, low or very low quality evidence can lead to a strong recommendation.*[51]

The methodology adopted by the BPW document will thus, predictably, conclude that any body of scientific literature that does not contain RCTs is "low" in quality. The 30 pages that it takes the authors to lay out their methodology is thus extremely misleading: a knowledgeable reader

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[48] BPW document, Results Section, p. 1.

[49] For example, the BPW document states that there is *evidence* about the effect of puberty blockers compared to not using puberty blockers. In other words, no studies compared the outcomes between a group of people with gender dysphoria using puberty blockers and another group of people with gender dysphoria not using them. Therefore, it is unknown whether people with gender dysphoria who use puberty blockers experience more improvement in gender dysphoria, depression, anxiety, and quality of life than those with gender dysphoria who do not use them. BPW document, Results section, p. 4.

[50] See Howard Balshem et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clinical Epidemiology P401-406 (2011), Table 3, p. 404

[51] Balshem et al., supra note 50, at 402 (emphasis added).

would know that if there are few or no RCTs in the literature, then the BPW technical conclusion is foregone, and, as importantly, is not a sound guide for clinical recommendations.

Put in simpler terms, if we coded apples as "high quality fruit" and bananas as "low quality fruit," then any fruit bowl that has only bananas would predictably be technically coded as "low quality." But that technical conclusion conveys very little information without context. For example, if no apples exist, then bananas may be a nutritious choice.

The drafters of the GRADE system emphasize that technically "low quality" evidence can support a strong clinical treatment recommendation. For example, pediatricians now agree – and every parent has been told -- that children should not be given aspirin for fevers. This recommendation is based on observational studies that showed an association between aspirin treatment during viral illnesses and the development of Reyes syndrome (a rapid and progressive disease of neurological dysfunction that can be fatal). Based on those studies, it would be unethical to conduct an RCT giving some children aspirin, and so the strong, consensus treatment recommendation is based entirely on "low quality" studies.[52]

The critical fact is that RCTs are not, and cannot be, the gold standard for medical research on gender dysphoria, due to strong ethical constraints. Medical care has long been shown, by reliable scientific methods, to address gender dysphoria and improve mental health: as we have repeatedly noted, these treatments have been recommended by rigorous clinical practice guidelines issued by WPATH and the Endocrine Society and endorsed by every major medical organization. Given this medical consensus, which is based on solid scientific evidence, it would be unethical to conduct an RCT that involved denying standard medical care to a control group of individuals.

It is thus simply a mistake – and a mischaracterization of medical research – to conclude that the absence of RCTs means that there is "no evidence" for the efficacy of medical treatment for gender dysphoria.

3. The June 2 Report reflects a faulty understanding of statistics, medical regulation, and scientific research, and it repeats discredited claims and engages in speculation and stereotyping without scientific evidence. The report therefore provides no scientific support for the Proposed Rule or for an interpretation of existing Florida Medicaid standards.

The June 2 Report provides no credible scientific support for the Proposed Rule, because its analysis is full of errors and misstatements. In this section, we offer seven examples, all of which are documented in more detail in the Appendix to these comments.

> A. The June 2 Report repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the June 2 Report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

[52] Balshem et al., supra note 50, at 402.

In its opening words, the June 2 Report makes an error that is repeated throughout the document: "Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased."

As we document in Section 2.B., above, it is an outright mistake to conclude that a study in the technical category of "low quality" is unreliable or poor evidence for clinical practice.[53] We provide additional analysis of the misuse of this language in the June 2 Report in the Appendix.

It is quite common for consensus medical practices to be supported only by technically "low quality" but respected observational studies – without RCTs. For example, the famous Framingham Heart Study provided the framework for clinical practice guidelines that support the use of statins, a cholesterol-lowering drug that is effective in preventing cardiovascular death.[54]

The statins example shows that the June 2 Report rests on a fundamental misunderstanding of medical research and clinical practice. If the Florida Medicaid program actually adopted the standard of evidence urged by the June 2 report, the program would not cover statins, which are prescribed to 28% of adults over the age of 40.[55] Other common practices that would have to be reconsidered under this logic include post-menopausal hormone replacement therapy (which reduces lifetime risk of heart attacks and stroke) and mammography screening for breast cancer.

The same point is true of the technically "low quality" evidence base for many surgical procedures, including minimally invasive gall bladder surgery, which has a solid evidence base in observational studies. We think it unlikely that Florida's Medicaid program will begin to refuse to pay for statins, mammograms, and routine surgeries. If not, then the June 2 Report and the Proposed Rule reflect an untenable and discriminatory double standard.

> B. The June 2 Report disregards robust clinical research studies and instead relies on sources with no scientific credibility. The report's analysis fails to satisfy Florida's own regulatory standards for Medicaid coverage decisions and provides no scientific foundation for the Proposed Rule.

The June 2 Report repeatedly cites sources with little or no scientific credibility – including journalism, a student blog, a website, and letters to the editor – rather than peer-reviewed empirical research, in violation of Florida's own regulatory standards.[56] At the same time, the

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[53] Balshem et al., supra note 50, at 404 ("Well-conducted studies may be part of a body of evidence rated low quality because they only provide indirect or imprecise evidence for the question of interest.")

[54] Neil J. Stone, et al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Red uce Atherosclerotic Cardiovascular Risk in Adults, 129(25) Circulation S1 -S45 (2014).

[55] Joseph A. Salami et al., National Trends in Statin Use and Expenditures in the U.S. Adult Population Fr m 2002 to 2013, 2(1) JAMA Cardiology 56-65 (2017).

[56] Sources from journalism include Jon Brown, Medical Textbook Strips Gender Dysphoria Definition after Being Cited by Florida, Fox News, May 8, 2022, at 8 https://www.foxnews.com/politics/textbook-strips-gender-dysphoria-definition-cited-florida [visited July 3, 2022; Lawrence S. Mayer and Paul McHugh, Sexuality and Gender: Finding from the Biological,Psychological, and Social Science, The New Atlantis (Fall 2016), https://www.thenewatlantis.com/wp-content/uploads/legacy-pdfs/20160819_TNA50SexualityandGender.pdf [visited July 3, 2022]. The citation to the student blog is Hong Phuong Nhi Le, Eminence-Based Medicine vs. Evidence-Based Medicine, Students 4 Best Evidence

report makes baseless or exaggerated criticisms of solid studies. Here, we offer only brief examples, with additional illustrations in the Appendix showing how selective and ungrounded criticism permeates the June 2 Report and further undermines its scientific credibility.

For example, the June 2 report attacks a 2015 study by Costa et al., claiming that the study design is flawed because it did not include a control group of adolescents without gender dysphoria.[57] This point is incorrect: as the Appendix to this report explains, the Costa et al. study did include an appropriate control group.

In addition to glaring technical errors, the June 2 Report's criticism of Costa makes an even more fundamental error: the June 2 report levels baseless criticisms at a single study *and fails to acknowledge that the weight of the literature as a whole strongly supports the same results Costa et al. report*. Scientific knowledge is, importantly, cumulative. It is thus entirely misleading – and unscientific – to dismiss the effectiveness of puberty blockers by criticizing studies in isolation. Put simply, the June 2 Report fails to acknowledge the number of solid studies that all find that puberty blockers are effective.[58] Indeed, at least 16 studies show that puberty blockers and hormones benefit patients with gender dysphoria, and the benefits have been documented across study designs, including retrospective report, cross sectional, longitudinal, and qualitative.[59]

The June 2 Report also grossly misleads the reader in its discussion of a study by Chen et al. in 2020[60] and a study by DeSanctis et al. in 2019.[61] The Appendix discusses these examples at

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[blog], https://s4be.cochrane.org/blog/2016/01/12/eminence-based-medicine-vs-evidence-based-medicine/#:~:text=What%20is%20eminence-based%20medicine [visited July 3, 2022]. The website is SEGM.org, which we discuss in the text in Section 2. Citations to letters and opinion pieces include, inter alia, Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020); Michael Laidlaw, et al., The Right to Best Care for Children Does Not Include the Right to Medical Transition, 19(2) Am. J. Bioethics 75-77 (2019); Michael Laidlaw, et al., Letter to the Editor: "Endocrine Treatment of Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Prace Guideline," 104(3) J. Clinical Endocrinology and Metabolism 686-687 (2018); Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020).

[57] June 2 Report, p. 15 ("Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control"). The Costa study is Rosalia Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 (11) J. Sexual Medicine P2206-2214 (2015) (hereinafter, "Costa et al. (2015)."

[58] See Luke R. Allen, et al., Well-Being and Suicidality Among Transgender Youth after Gender-Affirming Hormones, 7(3) Clinical Practice in Pediatric Psychology 302-11 (2019); Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70(4) J. Adolescent Health 643-649 (2022); Jack L. Turban, et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020); Maureen D. Connolly, et al., The Mental Health of Transgender Youth: Advances in Understanding, 59(5) J. Adolescent Health 489-95 (2016); Gemma L. Witcomb et al., Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services, J. Affective Disorders (2018)..

[59] For citations, see Boulware et al., supra note 36, at n. 43.

[60] Diane Chen, et al., Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth, Transgender Health 246-257 (2020).

[61] Vincenzo De Sanctis, et al., Long-Term Effects and Significant Adverse Drug Reactions (ADRs) Associated with the Use of Gonadotropin-Releasing Hormone Analogs (GnRHa) for Central Precocious Puberty: a Brief Review of Literature, 90(3) Acta Biomed. 345-359 (2019).

length. As a final example, the June 2 Report criticizes a 2019 preliminary study by Kuper et al. without acknowledging the existence of a more extensive 2020 study by Kuper et al.[62] The earlier study presented data on the mental health of adolescents when initially presenting for care; only the later study presented full data that demonstrated the benefit of treatment.

C. The June 2 Report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as here, is extremely common in medical practice and especially in pediatrics.

The June 2 Report repeatedly notes that the FDA has not approved the use of puberty blockers and hormones for the treatment of gender dysphoria in minors.[63] The report infers that lack of FDA approval renders a treatment unauthorized and experimental, but this is false. Once again, the June 2 Report (mis)uses technical language to confuse readers.

The term "off-label" has a very specific meaning: a drug is off-label if the FDA has not approved a particular medication for a particular use in a specific population. The off-label use of medications for children is common and often necessary, because an "overwhelming number of drugs" have no FDA-approved instructions for use in pediatric patients.[64]

The lack of FDA approval does not imply that the use of medications should be restricted. There is a consensus in the medical community that off-label use is necessary because of limits imposed by burdensome and expensive regulatory processes. Pharmaceutical companies often lack financial incentives to support research required for FDA approval for specific use in children.[65]

The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs:

> The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, *the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use.* Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient.[66]

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[62] June 2 Report, p. 16. The earlier Kuper et al. study is Laura E. Kuper et al., Baseline Mental Health and Psychosocial Functioning of Transgender Adolescents Seeking Gender-Affirming Hormone Therapy, 40(8) J. Dev. Behav. Pediatr. 589-596 (2019). The later study is Laura E. Kuper et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).
[63] June 2 Report, pp. 8, 14, 15, 19.
[64] Boulware et al, supra note 36, quoting Kathleen A. Neville, et al., American Academy of Pediatrics Committee on Drugs, Off-label use of drugs in children, 133(3) Pediatrics 563-7 (2014) ("AAP Committee on Drugs")
[65] AAP Committee on Drugs (2014), supra note 64.
[66] AAP Committee on Drugs (2014), supra note 64 (emphasis added). See also Lenneke Schrier, et al., Off-label Use of Medicines in Neonates, Infants, Children, and Adolescents: a Joint Policy Statement by the European Academy of Paediatrics and the European Society for Developmental Perinatal and Pediatric Pharmacology, 179(5) Eur. J. Pediatr 839-845 (2020).

Off-label use is so common in pediatrics that off-label drugs are prescribed in 20% of patient visits.[67] We discuss numerous examples in the Appendix, but a few familiar examples provide illustrations of day-to-day, off-label use in pediatrics.[68]

As many parents know, the use of steroids for croup is a life-saving treatment that is off-label. The medication helps toddlers get through severe, potentially airway-obstructing illnesses safely. Ondansetron (Zofran) is used off-label for nausea and vomiting to prevent dehydration.

In psychiatry, some of the most commonly-prescribed medications for youth are off label. For example, selective serotonin reuptake inhibitors (SSRIs) are used to treat major depressive disorder in adolescents and have been shown to be effective, even though several are off-label.[69] Another common example is clonidine, which is FDA-approved for attention deficit hyperactivity disorder (ADHD) but is used off-label for anxiety, insomnia, and post-traumatic stress disorder (PTSD).[70]

Finally, the June 2 Report notes that testosterone is a controlled substance and is subject to risk of abuse, but, once again, this is misleading. The inclusion of testosterone on the schedule of controlled substances reflects the misuse of the drug by some individuals and communities (e.g., weightlifters and athletes who may use the drug to build muscle). The classification does not in any way imply that physicians should not dispense the drug if medically necessary. No special license is necessary for prescribing the medication, which is routinely prescribed to cisgender men with testosterone deficiency.

> D. The June 2 Report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The June 2 Report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity. Below, we analyze two related claims made in the report and show why both are refuted by sound evidence. We provide additional detail in the Appendix.

First, the report claims that "the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex."[71] This is false. We have refuted this claim in detail in prior work. The key point is that *adolescents with gender dysphoria rarely find*

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[67] Diya Hoon, et al., Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015, 144(4) Pediatrics 1-10 (2019) (emphasis added).
[68] These examples are drawn from the list of off-label uses in AAP Committee on Drugs (2014) and reflect our clinical experience in major hospitals and clinics.
[69] For AACAP guidelines, see Boris Birmaher and David Brent, Practice Parameter for the Assessment and treatment of Children and Adolescents with Depressive Disorders, 46(110 J. Am. Acad. Child and Adolescent Psychiatry P1503-1526 (2007).
[70] Rama Yasaei and abdolreza Saadabadi, Clonidine, National Library of Medicine (2022), at https://www.ncbi.nlm.nih.gov/books/NBK459124/[visited July 4, 2022].
[71] June 2 Report, p. 14.

that their dysphoria resolves without treatment.[72] Because medical treatment for gender dysphoria begins only in adolescence, and only if medically necessary, medical treatment is thus provided only to a group known to be quite stable in their gender identity.

Second, the June 2 report claims that many transgender people regret their medical treatment. This is false. We provide a detailed discussion in the Appendix, but the scientific evidence is clear: solid studies show very low percentages of regret (typically under 1%) among transgender people who receive medical treatment for gender dysphoria. For example, Bustos et al. (2021) found regret expressed by one percent or fewer of transgender patients who underwent gender-affirming surgery, and Danker et al. (2018) report a rate of far less than 1%, as do Wiepjes et al. (2015).[73]

E. The June 2 Report repeats discredited claims that "social contagion" is leading teens to become transgender. Scientific evidence refutes this claim, which is based on a single, discredited study whose results have not been replicated by more rigorous studies.

The June 2 Report claims that "social factors (e.g., peer influences and media) may be contributing factors to gender dysphoria,"[74] citing as evidence a single, discredited study by Littman. We have addressed this claim at length in other work and note that the study incorporated such serious methodological errors that the journal of publication required an extensive correction because of the article's misstatements. [75]

Littman's sensationalist hypothesis has been widely covered in the press, but no clinical studies have found that rapid-onset gender dysphoria exists. Further, no professional organization has recognized "rapid-onset gender dysphoria" as a distinct clinical condition or diagnosis.

Most recently, an April 2022 study of 173 youth presenting at Canadian gender clinics *found no evidence of rapid-onset dysphoria or social contagion.* The researchers posited that if "rapid onset" gender dysphoria were a real phenomenon, then teens who had more recently begun identifying as transgender would (per the Littman hypothesis) also be more likely to report online support and engagement in their gender identity. They might also (per Littman's hypothesis) be more likely to struggle with mental health concerns**.**

An April 2022 study of 173 youth found no such correlations, strongly undercutting the "rapid-onset" hypothesis endorsed by the June 2 report. The researchers controlled for age and sex assigned at birth and looked for correlations with recent gender knowledge (defined as less than one to two years having passed since "you realized your gender was different from what other people called you"). Recent gender knowledge was *not* significantly associated with depressive symptoms, psychological distress, past diagnoses with comorbid mental health issues or neurodevelopmental disorders, or self-harm. Nor was it associated with having gender-

[72] Boulware et al., supra note 36, at 17-19.
[73] Id.
[74] June 2 Report, p. 12.
[75] Boulware et al., supra note 36, at 20-21 (internal citations omitted).

supportive online friends, general support from online friends or transgender friends, or gender support from parents.[76]

Data do substantiate that younger people today are more likely to identify as transgender than are older people, but this does not substantiate the idea of social contagion. The increase may be due to a cohort effect associated with the increasing social acceptance of gender diversity (i.e., older people grew up in a much more restrictive and transphobic social environment). In fact, adolescent presentation of transgender identity is often observed and should not be pathologized.[77]

Further, the data do not show a massive wave of transgender identity even among teens. A 2022 study by the Williams Institute found that, using an expansive definition of "transgender," about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people.[78] This is not a large percentage or a large absolute number.

The June 2 Report's social contagion claim also disregards the enormous social pressure on teenagers to adopt a cisgender identity; transgender teens face significant discrimination and violence by asserting their gender identity and report very high rates of bullying at school.[79] Further, the evidence shows that teens (like adults) tend to use social media for emotional support and to access a helpful peer group that may not be available in person.[80]

Ultimately, however, the social contagion hypothesis is irrelevant to the question whether medical care for gender dysphoria is effective. As we have noted, medical treatments are not offered to all gender-questioning youth. Instead, the WPATH and Endocrine Society standards recommend drug therapies for transgender adolescents whose interdisciplinary medical team has determined that they have lasting and intense gender dysphoria and that treatment is medically necessary.

> F. The June 2 Report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

The June 2 Report speculates that because "a high proportion" of youth receiving medical care for gender dysphoria also have a behavioral health disorder, "available research raises

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[76] Greta R. Bauer, et al., 243 J. Ped iatrics 224-227 (2022).

[77] In the largest U.S. sample of transgender adults, over half reported first starting to realize that they were transgender in adolescence (57% ages 11-20) and roughly half (47%) started to disclose their identity during this time frame. Sandy E. James, et al., The Report of the 2015 U.S. Transgender Survey, National Center for Transgender Equality (2015).

[78] Jody L. Herman, et al., How Many Adults and Youth Identify as Transgender in the United States?, U.C.L.A. School of Law, Williams Institute (2022).

[79] See, Joseph G. Kosciw, et al., The 2019 National School Climate Survey, GLSEN (2019), https://www.glsen.org/sites/default/files/2021-04/NSCS19-FullReport-032421-Web_0.pdf [visited July 3, 2020].

[80] Ashley Austin, et al., It's My Safe Space: The Life -Saving Role of the Internet in the Lives of Transgender and Gender Diverse Youth 21(1) Int'l J. Transgender Health 33-44 (2020); Ellen Selkie, et al., Transgender Adolescents' Uses of Social Media for Social Support, 66(3) J. Adolescent Health 275-280 (2020).

questions as to whether the [individuals'] distress is secondary to pre-existing behavioral health disorders and not gender dysphoria."[81] In simpler terms, the June 2 Report speculates that perhaps gender dysphoria is not real but is, rather, an imagined by-product of underlying mental illness.

A close examination shows that this claim has no foundation in science; it rests on unexamined and harmful stereotypes and unaccountably dismisses the scientific knowledge and clinical skill of child and adolescent psychologists and psychiatrists. Here, we briefly explain why the June 2 Report's speculations are scientifically unfounded. We provide further detail on these points in the Appendix.

The June 2 Report implicitly posits that behavioral health disorders cause gender dysphoria, but this hypothesis is completely unsupported by scientific evidence, which strongly suggests that the direction of causation runs the other way. It is well-established that being transgender leads to mental health concerns because of the social stress and discrimination of being transgender in our society.[82] Although the effects of gender minority stress are well-known, the June 2 Report makes no mention of the literature.

Further, the co-occurrence of psychological distress among individuals with gender dysphoria provides no reason for denying care. Any population of individuals – cisgender or transgender -- will include some with mental health concerns. In response, the WPATH and Endocrine Society guidelines include a careful psychological assessment of each adolescent as part of the process for determining whether medical treatment for gender dysphoria is appropriate.

Importantly, experts in child and adolescent psychiatry, child psychology, and adolescent medicine have established that youth – including youth with mental health conditions -- can make complex medical decisions. The scientific literature specifically demonstrates that transgender youth with co-occurring mental health conditions can competently participate in medical decision-making.[83]

> G. The June 2 Report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies.

The June 2 Report argues, without scientific evidence, that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy, an approach that

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[81] June 2 Report, p. 6.
[82] Rylan J. Testa, et al., Development of the Gender Minority Stress and Resilience Measure, 2(1) Psychology of Sexual Orientation and Gender Diversity 65-77 (2015); Rylan J. Testa, et al., Suicidal Ideation in Transgender People: Gender Minority Stress and Interpersonal Theory Factors, 126(1) J. Abnormal Psychology 125-36 (2017); Alexandrai M. Delozier, et al., Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review from a Minority Stress Framework, 45(8) J. Pediatric Psychology 842-847 (2020); Jessica Hunter, et al., Gender Minority Stress in Trans and Gender Diverse Adolescents and Young People, 26(4) Clinical Child Psychology and Psychiatry 1182-1195 (2021).
[83] Lieke J. Vrouenraets, et al., Assessing Medical Decision-Making Competence in Transgender Youth, 148(6) Pediatrics e2020049643 (2021).

it mistakenly terms "watchful waiting."[84] This statement is false. Here we provide an overview of the actual science, with more detail in the Appendix.

Several solid, recent studies have demonstrated that medical care for gender dysphoria has positive effects on mental health that are not associated with psychotherapy alone. Costa et al. in 2015 found that puberty blockers improve psychosocial functioning in teens with gender dysphoria, compared to teens who receive psychotherapy but not blockers.[85] In a 2022 study, Tordoff et al. clearly found that youth with gender dysphoria reported better outcomes if they received puberty blockers, even after controlling for the effects of psychotherapy.[86] A 2020 study by Laura Kuper et al. also shows that hormone treatment for gender dysphoria is effective above and beyond the benefits of psychotherapy and psychiatric medications. [87]

Conclusion

Our analysis demonstrates that the June 2 Report carries no scientific weight. The report disregards established clinical guidelines and peer-reviewed studies and instead relies on purported "expert" reports that raise major red flags for lack of expertise, close ties to advocacy groups, and financial conflicts of interest. The report makes repeated errors about scientific research and medical regulation, and it engages in ungrounded speculation and stereotyping.

Accordingly, the Proposed Rule is ungrounded in scientific research and is arbitrary and capricious. Further, because the June 2 report violates Florida's own standards for scientific review, it cannot support the Proposed Rule as an interpretation of the existing Florida regulatory scheme.

We respectfully submit this letter of comment for your consideration.

Very truly yours,

Anne L. Alstott

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[84] For example, at p. 12, the June 2 Report asks, "[S] hould conventional behavioral health services be utilized without proposing treatments that pose irreversible effects [i.e., drug therapies]? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects {i.e., the watchful waiting approach)?" At p. 20, t he June 2 Report misuses the term "watchful waiting" to describe the denial of medical care to adolescents with gender dysphoria, and the report miscites its own purported expert report. The Cantor document discusses "watchful waiting" meaning the denial of social transition to prepubertal children, not the denial of medical treatment to adolescents. Cantor document, p. 10-11.

[85] Costa et al., supra note 57.

[86] Diana M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender - Affirming Care, 5(2) JAMA Network Open e220978 (2022).

[87] Laura E. Kuper, et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

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Appendix

July 8, 2022

A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria

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Introduction

On June 2, 2022, the Florida Agency for Health Care Administration ("AHCA") issued a purported scientific report (hereinafter, "June 2 Report") concluding that standard medical care

* The authors have received no funding for this report or for our public comments on Florida's proposed Medicaid rule. We have no conflicts of interest to declare. Dr. Olezeski prepared paid expert testimony in a case for the Federal Public Defender for the District of Connecticut. We thank Melisa Olgun for excellent research assistance.

for gender dysphoria does not meet generally accepted medical standards and is experimental and investigational.[88]

We are a group of seven scientists and a law professor, and we have concluded, after a careful examination of the June 2 Report, that its conclusions are incorrect and scientifically unfounded. The June 2 Report purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unscientific.

We are alarmed that Florida's health care agency has adopted a purportedly scientific report that so blatantly violates the basic tenets of scientific inquiry. The report makes false statements and contains glaring errors regarding science, statistical methods, and medicine. Ignoring established science and longstanding, authoritative clinical guidance, the report instead relies on biased and discredited sources, including purported "expert" reports that carry no scientific weight due to lack of expertise and bias.

So repeated and fundamental are the errors in the June 2 Report that it seems clear that the report is not a serious scientific analysis but, rather, a document crafted to serve a political agenda.

The AHCA has offered the June 2 Report as justification for a proposed rule that would deny Florida Medicaid coverage for gender dysphoria to people of all ages (the "Proposed Rule").[89] We strongly oppose the Proposed Rule and have documented our reasons in public comments submitted to the AHCA on July 8, 2022. This report provides our detailed reasons for concluding that the June 2 Report provides no scientific support for Florida's proposed action.

Executive Summary

As we note in our comments on the Proposed Rule, we strongly oppose Florida's proposal to deny Medicaid coverage to standard medical care for gender dysphoria. In this report, we show that the June 2 Report is so thoroughly flawed and biased that it deserves no scientific weight. Although our focus is on the science, we also note that the Proposed Rule would violate the sex discrimination protections provided by the U.S. and Florida Constitutions and the federal statute that governs Medicaid by discriminating against transgender people on the basis of their sex, transgender status, and gender identity.[90]

In this report, we examine closely the "scientific" claims made in the June 2 Report, and we show that its basic conclusion is incorrect. Medical treatment for gender dysphoria does meet generally accepted professional medical standards and is not experimental or investigational. We also show that the June 2 report reflects a faulty understanding of statistics, medical regulation, and scientific research. The report ignores solid scientific evidence and instead

[88] Division of Florida Medicaid, Agency for Health Care Administration, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, June 2022, at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf("June 2 Report").
[89] 48 Fl. Admin. Reg. 2461 (June 17, 2022).
[90] See Bostock v. Clayton County, 590 U.S. __ (2020); Kadel v. Folwell, M.D. N.C., Mem. Op. 6-10-22 (applying Bostock to public health plan coverage); 42 U.S.C. 18116 (requiring nondiscrimination in Medicaid plans).

repeats discredited claims, cites to sources with no scientific merit, and engages in unfounded speculation based on stereotypes rather than science.

Specifically, we show that:

- Contrary to the June 2 Report's repeated claims, medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.
- The June 2 Report appears to be a scientific report, but its veneer hides a flawed analysis that ignores the scientific evidence and relies instead on pseudo-science, particularly purported "expert" reports that are biased, inexpert, and full of errors. The claimed "expert" reports are written by authors whose testimony has been disqualified in court and who have known ties to anti-LGBTQ advocacy groups.
- Nothing in the June 2 Report calls into question the scientific foundations of standard medical care for gender dysphoria. The June 2 Report makes unfounded criticisms of robust and well-regarded clinical research and instead cites sources with little or no scientific merit, including journalism, a blog entry, letters to the editor, and opinion pieces.
- The linchpin of the June 2 Report is an analysis by two epidemiologists that claims to undermine the scientific evidence supporting medical care for gender dysphoria. Their analysis is extremely narrow in scope, inexpert, and so flawed that it merits no scientific weight at all.
- The June 2 Report repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the June 2 Report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cardioprotective cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

I. Contrary to the June 2 Report's repeated claims, medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.

The conclusion of the June 2 report – that medical treatments for gender dysphoria "do not conform to [generally accepted professional medical standards] and are experimental and investigational"[91] – is demonstrably false.

Medical care for the treatment of gender dysphoria, which for youth under the age of majority can include gonadotropin releasing hormone agonists ("GnRHa" or puberty blockers) and hormone therapy, has been vetted and approved by international bodies of experts based on the scientific evidence. Two authoritative bodies of scientists, the World Professional Association for Transgender Health (WPATH) and The Endocrine Society, have published extensive clinical practice guidelines for treating gender dysphoria.[92] These clinical guidelines are based on

[91] June 2 Report, p. 2.
[92] See Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Professional Association for Transgender Health (7th version, 2012), at https://www.wpath.org/publications/soc ("WPATH (2012)"); Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent

rigorous, structured processes that include a committee of scientific experts and peer review by additional experts. The guidelines are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments.

These longstanding clinical practice guidelines have been used by clinicians for decades. WPATH issued its initial guidelines in 1979 and updated them in 1980, 1981, 1990, 1998, 2001, and 2012. The eighth version remains in process, and it incorporates systematic literature reviews and ample opportunities for peer review and revision.[93] The original Endocrine Society guidelines were published in 2009 and updated in 2017.[94]

Reflecting this scientific and medical consensus, medical care for gender dysphoria has been confirmed as standard care by every relevant medical organization in the United States, including the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry.[95] In 2022, these organizations united with the American Medical Association, the American College of Obstetricians and Gynecologists, and other groups to file an amicus brief representing a total of 20 major medical societies. The brief reaffirms that puberty blockers and hormone treatments for gender dysphoria are standard medical care and opposes legal measures that would limit patient access to this standard care.[96]

The weight and volume of these endorsements, across diverse medical specialties, sharply contradicts the June 2 Report's conclusions.

II. The June 2 Report appears to be a scientific report, but its veneer hides a flawed analysis that ignores the scientific evidence and relies instead on pseudo-science. The report heavily relies on five purported "expert" documents that are biased, inexpert, and full of errors.

The Florida report dismisses or ignores the WPATH and Endocrine Society clinical practice guidelines and the science that underlies them and instead relies on five attached documents that, the report claims, constitute "clinical and technical expert assessments."[97]

Persons: An Endocrine Society Clinical Practice Guideline, 102(11) J. Clin. Endocrinol. Metab. 3869-3903 (2017) ("Endocrine Society (2017)").

[93] See World Professional Association for Transgender Health (WPATH), Methodology for the Development of Standards of Care 8 (Soc 8), at https://www.wpath.org/soc8/Methodology

[94] Endocrine Society (2017), supra note 5.

[95] Jason Rafferty, Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142(4) Pediatrics E20182162 (2018); American Psychological Association, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70(9) American Psychologist 832-64 (2015); Stewart L. Adelson, Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, 51(9) J. Am. Acad. Child & Adolescent Psychiatry, 957 -974 (2012).

[96] Brief of Amicus Curiae American Academy of Pediatrics and Additi onal National and State Medical and Mental Health Organizations in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction, Eknes-Tucker v. Ivey (later redesignated Eknes-Tucker v. Abbott), May 5, 2022, at https://www.aamc.org/media/60556/download

[97] June 2 Report, p. 2.

Despite their billing as "expert" reports, the attachments to the June 2 report are unpublished, non-peer-reviewed documents written by authors with questionable claims to expertise and with red flags for undisclosed author bias. These documents should be given no weight in a serious scientific process.

> A. The purported "expert" documents attached to the June 2 Report carry no scientific weight. They are unpublished and not peer-reviewed, and they are written by authors whose expertise has been successfully challenged in legal proceedings and whose backgrounds raise red flags for bias.

None of the documents attached to the June 2 Report meet standard criteria for expert scientific investigations, because none is published or peer reviewed. Publication and peer review are fundamental to science, as they ensure that a scientist's data and conclusions are open to scrutiny from scientific experts.

Florida's own standards for the determination of medical necessity recognize this point when they state that determinations of Medicaid coverage must consult "*published* reports and articles in the authoritative medical and scientific literature related to the health service (*published in peer-reviewed scientific literature* generally recognized by the relevant medical community or practitioner specialty associations)."[98] It is thus both unscientific and a violation of the regulations for the June 2 Report to rely on the unpublished documents as its principal evidence base.

Further, the attachments all raise red flags for author bias. The June 2 Report does not disclose how these "experts" were identified or by what criteria their expertise was assessed. The opacity of the Florida AHCA process for identifying experts is particularly troubling because at least four of the experts have strong indications of bias. Further, the qualifications and credibility of two of the experts have been successfully challenged in litigation.[99] Two of the expert reports duplicate, word-for-word (or with very slight edits) testimony that was offered, apparently for pay, in litigation. Both have connections to advocacy organizations that oppose LGBTQ rights across the board. The endorsement of these individuals as Florida's banner "experts" raises the appearance of bias – that the AHCA sought a pre-ordained outcome, not a true scientific perspective.

Adding to these red flags for bias, none of the authors of the attachments provide a statement of funding and conflicts of interest. This omission violates a strong norm in scientific writing, which requires authors to declare any conflicts of interest; these include any professional or financial arrangements that could call into question their independence of judgment.[100] That

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[98] Fl. Admin. Code Section 59G-1.035(4).

[99] See Stephen Caruso, A Texas Judge Ruled That This Doctor Was Not an Expert, Pennsylvania Capital-Star, Sept. 15, 2020 (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed).

[100] For example, the conflict of interest rules for JAMA, one of the premier medical journals in the United States and the world state that "[a]uthors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript) including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers' bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued." JAMA Network, Instructions for Authors, visited June

strong norm also requires authors to disclose whether projects have been funded and if so, by whom and whether the authors have engaged in expert testimony. Without these statements, the Florida AHCA and the public cannot detect biases that could affect the integrity of these written products.

These are more than theoretical concerns: at least four of the attachments have notable indicators of conflicts of interest and bias. (Note that these are the only four we examined in detail, and so we do not imply that the other one is free from such bias.)

The author of the document provided as Attachment E is Quentin van Meter, whose history indicates bias and lack of expertise. Although the AHCA presents van Meter as an expert in medical treatment for gender dysphoria, at least one court barred him from providing expert testimony on the issue.[101] Van Meter is the president of the American College of Pediatricians (the "ACP"), which presents itself as a scientific group (and might be confused, by a non-expert, with the authoritative American Academy of Pediatrics). The ACP is, in fact, a political group that opposes same-sex marriage,[102] supports mental health providers practicing conversion therapy,[103] and describes childhood gender dysphoria as "confusion."[104] Troublingly, the van Meter attachment, proffered by the AHCA as a scientific report, contains several passages of uncredited, verbatim language that appears in a "position statement" published by the ACP.[105] The van Meter attachment appears to be a re-use of paid testimony rather than an original product.[106]

James Cantor's document, presented as Attachment D to the June 2 Report, also faces serious questions about bias and lack of expertise. In a 2022 case, a federal court took a skeptical view of Cantor's purported expertise, noting that "the Court gave [Cantor's] testimony little weight because he admitted, inter alia, to having no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria.[107]

22, 2022, at https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecConflictsofInterestandFinancialDisclosures

[101] Caruso, supra note 12.

[102] Den Trumbull, Defending Traditional Marriage, American College of Pediatricians (2013), https://acpeds.org/position-statements/defending-traditional-marriage. See Jack Turban, The American College of Pediatricians is an Anti-LGBTQ Group, Psychology Today, May 8, 2017.

[103] Christopher Rosik and Michelle Cretella, Psychotherapy for Unwanted Homosexual Attraction Among Youth, American College of Pediatricians (2016), https://acpeds.org/position -statements/psychotherapy-for-unwanted-homosexual-attraction-among-youth.

[104] Michelle Cretella, Gender Dysphoria in Children, American College of Pediatricians (2018), https://acpeds.org/position-statements/gender-dysphoria-in-children (site visited June 22, 2022). The author of the ACP position paper is Michelle Cretella, who was publicly rebuked by the Society for Adolescent Health and Medicine, the leading society for adolescent medicine in the United States, for "pushing political and ideological agendas not based on science and facts." https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-(2).aspx

[105] The similarity was shown by a Word comparison of the van Meter report provided as Attachment E to the June 2 Report with a "position statement" published on the ACP website, with authorship credit given on the website to Michelle Cretella. See Michelle Cretella, Gender Dysphoria in Children, supra note 17.

[106] The van Meter document attached to the June 2 Report is substantially identical to his expert declaration in Adams v. School Board of St. Johns County, Florida. https://files.eqcf.org/wp-content/uploads/2017/12/41-D-AMENDED-Notice-Documents-iso-Response-to-PI.pdf.

[107] Opinion and Order, Eknes-Tucker v. Marshall, 2:22-CV-184-LCB, M.D. Alabama, May 13, 2022.

Cantor's document is nearly identical to what appears to be paid testimony in another case, where Cantor's declaration was used to support legislation barring transgender athletes from sports teams,[108] Troublingly, Cantor's appearance in that case seems to have been funded by the Alliance Defending Freedom ("ADF"), [109] a religious and political organization that opposes legal protections for transgender people and same-sex marriage[110] and defends the criminalization of sexual activity between partners of the same sex.[111] Because Cantor provides no conflicts of interest disclosure, readers cannot ascertain whether Florida AHCA also paid for Cantor's report and whether Florida officials were aware that the Cantor report reused his work for (apparently) the ADF.

Romina Brignardello-Petersen is one of two authors of the document provided as Attachment C to the June 2 Report. Although Brignardello-Petersen claims to have no research interests in medical care for transgender youth,[112] she has conducted research for the Society for Evidence-Based Gender Medicine ("SEGM").[113] Although SEGM claims to be an international medical society, it is actually an activist group that opposes standard medical care for gender dysphoria. The SEGM has no publications or conferences and seems to consist solely of a website created by a small group of people with limited or no scientific credentials or clinical experience. The site presents a cherry-picked collection of studies and narrative content that is full of scientific errors.[114]

Patrick Lappert, whose document is attached to the June 2 Report as Attachment F, has been disqualified as an expert in a recent federal court decision in North Carolina. [115] The judge found

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[108] The case is BPJ v. West Virginia State Board of Education, and the Alliance Defending Freedom takes credit for it here: https://adfmedia.org/case/bpj-v-west-virginia-state-board-education. Cantor's declaration appears here: https://adfmedialegalfiles.blob.core.windows.net/files/BPJ-CantorDeclaration.pdf

[109] The ADF seems to take credit for the case in this press conference notice: https://adfmedia.org/case/bpj-v-west-virginia-state-board-education

[110] Marriage is the Future, American College of Pediatricians, https://adflegal.org/issues/marriage/overview(site visited July 2, 2022. Content on the page includes this statement: "Marriage is about equality and diversity. It's about joining the two equally important and diverse halves of humanity represented in men and women."

[111] Southern Poverty Law Center, Dangerous Liaisons, July 10, 2013, https://www.splcenter.org/20130709/dangerous-liaisons [visited July 2, 2022].

[112] Like the van Meter and Cantor attachments, the BPW document provides no express statement of conflicts of interest. The BPW document does offer a statement of "credentials and expertise," in which she declares that "her research interests are not in this area," meaning apparently research on medical care for gender dysphoria. BPW Document, p. 1.

[113] BPW document, p. 1. For one example of the purported research that Brignardello-Petersen apparently assisted in, see Alison Clayton et al., Commentary: the Signal and the Noise– Questioning the Benefits of Puberty Blockers for Youth with Gender Dysphoria– A Commentary on Rew et al. (2021), Child and Adolescent Mental Health, Dec. 22, 2021, at https://acamh.onlinelibrary.wiley.com/doi/10.1111/camh.12533 In the "Acknowledgements" section, the authors state, "We would also like to thank the Society for Evidence-based Gender Medicine (SEGM) for providing access to several experts who helped shape this commentary and ensure its accuracy. Specifically, we would like to thank Dr. Romina Brignardello Petersen [sic] for contributing her methodological expertise."

[114] Susan Boulware et al., Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims (April 28, 2022), at 28-29 (Appendix A) available at https://medicine.yale.edu/childstudy/policy-and-social-innovation/lgbtq-youth/.

[115] Kadel v. Folwell, 1:19CV272, M.D. N.C. June 10, 2022. The judge ruled that Lappert was not qualified to "render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments." Lappert was also

that evidence "calls Lappert's bias and reliability into serious question" and noted that Lappert has worked closely with ADF and has actively lobbied for legal bans on medical care for transgender youth.[116] The judge gave no weight to Lappert's testimony about informed consent in that case, finding that it was unsupported by scientific evidence.[117] The judge also found that "Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has "never been generally accepted by the relevant scientific community."[118]

B. The linchpin of the June 2 Report is the analysis by Brignardello-Petersen and Wiercioch (the "BPW document"), provided as Attachment C, which purports to be a comprehensive review of the scientific literature on medical treatment for gender dysphoria but, in fact, is extremely narrow in scope and so flawed in its analysis that it merits no scientific weight.

The BPW document, like the other attachments to the June 2 Report, is an unpublished, non-peer-reviewed document. It claims to conduct a systematic review of the relevant scientific literature, but in fact, it is written by inexpert authors who construct an arbitrarily truncated sample and adopt a method that violates scientific guidelines and produces a biased result. The authors describe their findings in deceptive language and jargon predictably mislead the reader. Our review shows that *nothing in the BPW document calls into question the scientific foundations of the WPATH and the Endocrine Society clinical practice guidelines.*

The BPW document seems scientific on its face, and it may be impressive to non-experts, because it uses technical jargon and includes numerous tables and charts. But a closer examination shows that it violates established standards for medical research and shows signs of being engineered to produce a pre-ordained and inaccurate result: the false claim that there is no scientific evidence base for medical treatment for gender dysphoria. Contrary to the authors' claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria and spans decades.

The bottom line is that, contrary to the BPW document's claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria.

(1) The BPW document lacks scientific credibility due to the authors' lack of relevant qualifications and their ties to an activist group.

The BPW document purports to be a systematic review of the scientific literature on medical treatment for gender dysphoria. But the document, like the other attachments to the June 2 Report, is not published or peer-reviewed, and its design and execution raise numerous red flags for bias. Here, we describe just four of the notable defects that undercut entirely the document's claim to objectivity and sound method.

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disqualified from opining on "the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria." Id.

[116] Id.

[117] Id., pp. 29-30.

[118] Id., p. 31.

First, neither of the BPW authors are experts in medical care for gender dysphoria, either as researchers or clinicians. One author (Brignardello-Petersen) has not previously studied the subject, except in her work for the ideological organization SEGM.org, noted just above. Her only clinical experience appears to be in dentistry.[119] The other author (Wiercioch) is a junior researcher (a postdoctoral fellow) with no prior research or clinical experience in this field.

The authors' lack of interest and experience renders the BPW work inexpert rather than objective, and it violates the National Academy of Medicine (formerly, Institute of Medicine) standards for systematic reviews. By analogy, one would not rely on, say, two dermatologists to conduct a review of the scientific literature on neurosurgery and to make recommendations for clinical practice.

Second, not only is the study not formally peer-reviewed, the BPW authors violate scientific norms and standards by *failing to engage at all with their peers or with actual experts in the subject matter*. As experts in research methodology should know, any sound systematic review should propose explicit and reproducible methods to methodically summarize the existing literature; the protocol (i.e., the research design) is then published to solicit input and criticisms from potential users of the review and experts in the field. Peer review of the literature review and publication of the protocol are not optional or merely window-dressing; they reflect bedrock commitments of the scientific method. These processes help ensure that the authors of any review understand the existing research and craft a research design that will usefully build on and add to prior work.

The BPW document violates these standards, raising questions about whether this was a rushed study designed to serve a political agenda – rather than a considered, comprehensive, scientific enterprise. The BPW document does not contain a review of the existing literature, and it does not acknowledge the WPATH and Endocrine clinical practice guidelines, which are themselves based on careful systematic reviews. The BPW authors appear not to have published their protocol in advance or otherwise to have submitted their protocol for peer review. That is, there is no indication that they vetted their research design in consultation with subject-matter experts.

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[119] Romina Brignardello bio, at https://experts.mcmaster.ca/display/brignarr [visited July 2, 2022]
Google Scholar, Wojtek Wiercioch, visited June 22, 2022, https://scholar.google.com/citations?user=vdi3r_AAAAAJ&hl=en
Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine, Finding What Works in Health Care: Standards for Systematic Reviews, National Academies (Jill Eden et al., eds 2011), p. 48 (Standard 2.1.1 states that teams for systematic reviews should include expertise in pertinent clinical content areas). Background: The Institute of Medicine, now called the National Academy of Medicine, is one of three branches of the National Academies of Science, Engineering, and Medicine. The National Academy of Science dates to 1963 and was established by Congress; the Institute of Medicine was established as a separate entity in 1970 and serves as the nation's leading authority on scientific research and knowledge. National Academy of Medicine, About the National Academy of Medicine, website visited June 22, 2022, https://nam.edu/about-the-nam/ The standards for systematic reviews were published in 2011, responding to a Congressional request to set benchmarks for high-quality systematic reviews that could reliably guide physicians and healthcare providers in making informed, scientific judgments about health care.
Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine, supra note 34, at pp. 72-75.

Third, the BPW document raises red flags for opinion bias. Buried in the methodology pages of the BPW document is the fact that the authors uncritically include politically biased "grey literature" sources, giving them equal weight to peer-reviewed, published literature. Specifically, the authors include in their search the fringe website SEGM.org. As noted above, the group's website posts are not peer-reviewed or published, and its content is assembled by a small group of activists with few or no expert credentials and is often full of errors. Troublingly, this is the group to which one of the authors, Brignardello-Petersen, has ties, as noted above.

> *(2) The BPW document examines a truncated sample of the literature and adopts a methodology that violates scientific standards for evaluating medical evidence. The authors compound this bias by describing their results using overstated and deceptive language. The picture that emerges is of a rushed and inexpert report with indications of bias.*

The BPW document has a patina of scientific expertise. It invokes the respected GRADE standards for rating the quality of studies, and it occupies many pages with tables and technical specifications. When a reader looks past the jargon, however, the BPW authors adopt a method that actually violates GRADE standards and appears to be jury-rigged to reach a foregone conclusion. The authors then convey their conclusions in misleading language. *Contrary to the BPW authors' claims, their study does not call into question the scientific and clinical importance of the established science that supports medical care for gender dysphoria.*

The BPW analysis incorporates numerous decisions that bias their results, and they make numerous misleading statements. First, the BPW document reviewed only a small sample of the relevant scientific literature. In the introduction, the BPW authors initially claim to have reviewed 61 systematic reviews of medical treatment for gender dysphoria. But buried in the middle of the document is the admission that the analysis is based on a sample of 27 systematic reviews, not 61 as claimed. The result is that the BPW analysis excludes a great deal of relevant evidence, and the authors provide no rationale for this "prioritization," as they call it. Troublingly, although the BPW document claims to be conducting a review of the literature that analyzes existing systematic reviews, the 27 studies they analyze are not all systematic reviews. Three of the 27 are mislabeled as systematic reviews but are actually practice bulletins, unpublished protocols or unlocatable.

Troublingly, the authors also embed in the middle of their document a*n unjustified decision to limit their analysis to studies published from 2020 to the present, and their project has strong indications that it was rushed work.* The authors disclose that they "prioritized" studies from the last 30 months (two full years plus four months in 2022), but they do not defend that priority.

BPW document, Methods section, p. 2.
See Boulware et al., supra note 27 pp. 28-29 (Appendix A).
BPW document, Introduction Section, p. 2.
BPW document, Results Section, p. 1.

The reader is left to wonder whether this truncation served only to help the authors produce their analysis in what was apparently a very short time frame.

The truncation of the literature sample to the period from 2020 to early 2022 is worrisome because that period coincides with the worst global public health emergency in generations. The pandemic disrupted many institutions, straining the health care system and putting immense pressure on clinicians. It is likely that the pandemic stalled the production and publication of non-COVID research during this period, calling into sharp question the BPW authors' sampling strategy.

The BPW sample is also questionable because the authors choose, without justification, a small subsection of databases to search and have likely missed important literature as a result. Specifically, they chose not to source from other important databases such as Embase, PsycInfo, Web of Science, Scopus, or Cochrane. They also limited their scope to works published in English only, an exclusion that can introduce bias.

Second, the BPW authors misused and mechanically applied a well-regarded rating system known as AMSTAR, which is intended to evaluate the methodological strength of systematic reviews. They misused this rating system because their so-called group of systematic reviews included documents that cannot correctly be included (practice bulletins, unpublished protocols, and unlocatable documents) and thus led to a negative bias. The BPW error is further amplified because the authors used the flawed results of the AMSTAR phase to inform their next level of analysis, the GRADE system (which assesses the quality of medical evidence of pooled systematic reviews). Based on this flawed and purely mechanical review of truncated sources, the BPW analysis reaches the conclusion that there is little or no evidence for the benefits of medical care for gender dysphoria.

The BPW analysis is highly deceptive, because it dismisses nearly all existing studies of medical treatment for gender dysphoria as "low quality," without explaining that this is a highly technical term and not a natural-language condemnation of the studies. By contrast, the GRADE system, which the authors purport to use, is quite clear about its quality rating systems and its limitations. In general, only randomized controlled trials (RCTs) are coded as "high" quality evidence in the GRADE system. A randomized controlled trial is a study that divides patients randomly into a control group (no treatment) and a treatment group. In contrast, an observational study records information about patients in a real-world setting that is more reliably generalizable, e.g., a cohort of patients seen at a clinic. Under the GRADE guidelines, observational studies are coded as "low" in quality.

The authors disclose that they conducted their initial literature searches– the first step in the review process– at the end of April 2022. BPW document, Methods section, p. 2.

For example, the BPW document states that there is *evidence* about the effect of puberty blockers compared to not using puberty blockers. In other words, no studies compared the outcomes between a group of people with gender dysphoria using puberty blockers and another group of people with gender dysphoria not using them. Therefore, it is unknown whether people with gender dysphoria who use puberty blockers experience more improvement in gender dysphoria, depression, anxiety, and quality of life than those with gender dysphoria who do not use them. BPW document, Results section, p. 4.

See Howard Balshem et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clinical Epidemiology P401 -406 (2011), Table 3, p. 404

The key point is that "low quality" in this context is a technical term and not a condemnation of the evidence, because "low quality" studies regularly guide important aspects of clinical practice. Indeed, the GRADE system, which the BPW document claims to use, specifically notes that GRADE should *not* be used to dismiss observational studies or to give absolute priority to RCTs:

> Although higher quality evidence is more likely to be associated with strong recommendations than lower quality evidence, a particular level of quality does not imply a particular strength of recommendation. *Sometimes, low or very low quality evidence can lead to a strong recommendation.*[130]

The methodology adopted by the BPW document will thus, predictably, conclude that any body of scientific literature that does not contain RCTs is "low" in quality. Had BPW begun, as they should have, with a literature review of the evidence on puberty blockers and hormones, they would have seen that the evidence consists primarily of observational studies (for the good reasons discussed below). Thus, the 30 pages that it takes the authors to lay out their methodology is misleading: a knowledgeable reader would know that if there are few or no RCTs in the literature, then the BPW technical conclusion is foregone and, as importantly, is not a sound guide for clinical recommendations.

Put in simpler terms, if we coded apples as "high quality fruit" and bananas as "low quality fruit," then any fruit bowl that has only bananas would predictably be technically coded as "low quality." But that technical conclusion conveys very little information without context. For example, if no apples exist, then bananas may be a nutritious choice.

The drafters of the GRADE system emphasize that technically "low quality" evidence can support a strong clinical treatment recommendation. For example, pediatricians now agree that children should not be given aspirin for fevers. This recommendation is based on observational studies that showed an association between aspirin treatment during viral illnesses and the development of Reyes syndrome (a rapid and progressive disease of neurological dysfunction that can be fatal). Based on those studies, it would be unethical to conduct an RCT giving some children aspirin, and so the strong, consensus treatment recommendation is based entirely on "low quality" studies.[131]

The critical fact is that RCTs are not, and cannot be, the gold standard for medical research on gender dysphoria. In the context of treatments for gender dysphoria, randomized controlled trials would often be inappropriate for ethical reasons. Medical care has long been shown, by reliable scientific methods, to address gender dysphoria and improve mental health: as we have repeatedly noted, these treatments have been recommended by rigorous clinical practice guidelines issued by WPATH and the Endocrine Society and endorsed by every major medical organization. Given this medical consensus, which is based on solid scientific evidence, it would be unethical to conduct an RCT that involved denying standard medical care to a control group of individuals.

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[130] Balshem et al., supra note 42, at 402 (emphasis added).
[131] Id.

Similar ethical issues, along with practical barriers, leave many areas of consensus medicine supported by observational studies and not RCTs. Many surgical procedures, for example, are not supported by RCTs.[132] Nor are standard protocols for lowering cholesterol using statins, one of the most widely-prescribed drugs in the United States. (See Section III.A of this report.)

It is thus simply a mistake – and a mischaracterization of medical research across fields of medicine – to conclude that the absence of RCTs means that there is "no evidence" for the efficacy of medical treatment for gender dysphoria. Medical research requires, instead, that researchers evaluate the design and conduct of specific observational studies and do so with an awareness of clinical context.[133]

In sharp contrast to BPW, this is precisely what the authors of the Endocrine Society did in their 2017 clinical guidelines, which use the GRADE system but, in addition, carefully discuss the characteristics of the studies supporting each treatment guideline.[134] The Endocrine Society discloses the GRADE rankings for each treatment recommendation in order to be transparent about the evidence base for each of its recommendations. Then, following National Academy of Medicine (formerly, Institute of Medicine) standards for clinical practice guidelines, they proceed to a qualitative review of the evidence, place the evidence in clinical context, and discuss openly the values at stake in making a clinical practice recommendation.[135]

III. The June 2 Report reflects a faulty understanding of statistics, medical regulation, and scientific research, and it repeats discredited claims and engages in speculation and stereotyping without scientific evidence.

The June 2 Report is full of errors and misstatements. Disregarding solid scientific evidence, the report relies on debunked studies and sheer speculation, and it levels criticisms at solid evidence that betray a poor understanding of medical research and statistics.

A. The June 2 Report repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the June 2 Report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

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[132] See, e.g., Peter McCulloch, et al., Randomised Trials in Surgery: Problems and Possible Solutions, 324 (7351) BMJ 1448-1451 (2002).

[133] See Balshem et al., supra note 42 at 405 ("[W] e caution against a mechanistic approach toward the application of the criteria for rating the quality of the evidence up or down…. Fundamentally, the assessment of evidence quality is a subjective process, and GRADE should not be seen as obviating the need for or minimizing the importance of judgment or as suggesting that quality can be objectively determined"). See also the National Institute of Medicine (Institute of Medicine) Standards, supra note 34, at 176: ("We are disappointed when a systematic review simply lists the characteristics and findings of a series of singlestudies without attempting, in a sophisticated and clinically meaningful manner, to discover the pattern in a body of evidence. Although we greatly value meta -analyses, we look askance if they seem to be mechanistically produced without careful consideration of the appropriateness of pooling results or little attempt to integrate the finds into the contextual background.")

[134] Endocrine Society (2017), supra note 5.

[135] Id.

In its opening words, the June 2 Report makes an error that is repeated throughout the document: "Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased."

As we document in Section II.B., above, it is an outright mistake to conclude that a study in the technical category of "low quality" is unreliable or poor evidence for clinical practice.[136] Thus, it is frank error for the June 2 Report to dismiss well-done, scientifically important studies because they rank as "low quality" using specialized, technical terms.

Like the BPW document, the June 2 Report thus relies on a deceptive use of technical terminology that is at odds with the standards used in medical research. It simply is not – and cannot be – the case that all clinical recommendations must be based on RCTs. Many areas of medicine do not lend themselves to ethical and practical RCTs. It is unethical to conduct an RCT when randomizing a patient to a control group would cause harm by denying treatments of known efficacy. For example, it would be unethical to conduct an RCT on the treatment of juvenile diabetes by randomizing some participants to receive insulin and others to receive no treatment.[137]

It is quite common for the medical community to adopt important, consensus clinical practices supported by observational studies alone. For example, observational studies, notably the famous Framingham Heart Study, provided the framework for clinical practice guidelines in prevention and treatment of cardiovascular disease. In 2013, the American College of Cardiology and the American Heart Association issued updated clinical practice guidelines on the treatment of cholesterol to reduce heart disease risk in adults (the "Cholesterol Guidelines").[138] These authoritative guidelines have been widely used in clinical practice but are based not only on RCTs but on a great deal of observational evidence, including studies technically ranked as "low quality."[139] Concretely, many of the original treatment recommendations regarding statins are based on observational studies, not RCTs.[140] The authors of the Cholesterol Guidelines, very much like the Endocrine Society authors, are quite careful to grade their evidence. But they do not rest their treatment guidelines on a mechanical assessment of technical quality. Instead, they (like the Endocrine Society) carefully explain why particular bodies of evidence should be given weight in clinical decisionmaking.

The cholesterol example shows that the June 2 Report rests on a fundamental misunderstanding of medical research and clinical practice. If the Florida Medicaid program actually adopted the standard of evidence urged by the June 2 report, the program would not cover statins (drugs to

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[136] Balshem et al., supra note 42, at 404 ("Well-conducted studies may be part of a body of evidence rated low quality because they only provide indirect or imprecise evidence for the question of interest.")
[137] RCTs have other limitations as well. For example, RCTs often have strict exclusionary criteria that recruit healthier and more homogenous study populations than observational studies. Thus, this can lead to results that are not easily generalizable in real-world settings.
[138] Neil J. Stone, et al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, 129(25) Circulation S1 -S45 (2014).
[139] Id., Tables 3 and 4.
[140] Syed S. Mahmood, et al., The Framingham Heart Study and the Epidemiology of Cardiovascular Disease: a Historical Perspective, 383 Lancet 999-1008 (2014).

lower cholesterol) for many patients, which are prescribed to 28% of adults over the age of 40 and are one of the most effective ways to prevent cardiovascular death.[141] Other common practices that would have to be reconsidered under this logic include: post-menopausal hormone replacement therapy (which reduces lifetime risk of heart attacks and stroke) and mammography screening for breast cancer.

The same point is true of the technically "low quality" evidence base for many surgical procedures, including minimally invasive gall bladder surgery, which have long since had a foundational grounding in observational studies. We think it unlikely that Florida's Medicaid program will begin to refuse to pay for statins, mammograms, and routine surgeries. If not, then the June 2 Report reflects an untenable and discriminatory double standard.

Thus, the June 2 Report not only relies on the biased and methodologically flawed evidence in the BPW document, as documented in Section II above; it also misuses scientific terminology in an effort to mislead readers and to support the unwarranted conclusion that medical treatment for gender dysphoria is "experimental."

B. The June 2 Report disregards robust clinical research studies and instead relies on letters to the editor and opinion pieces. The report's analysis fails to satisfy Florida's own regulatory standards for Medicaid coverage decisions and does not undermine the scientific research that supports medical treatment for gender dysphoria.

The June 2 Report repeatedly cites sources with little or no scientific credibility – including journalism, a student blog, a website, and letters to the editor – rather than peer-reviewed empirical research.[142] At the same time, the report makes baseless or exaggerated criticisms of solid studies. The report's objections to these studies incorporate mistakes about basic statistics and often misrepresent the aims and findings of studies. Here, we offer several examples, but the problem of selective and ungrounded criticism permeates the June 2 Report and further undermines its scientific credibility.

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[141] Joseph A. Salami et al., National Trends in Statin Use and Expenditures in the U.S. Adult Population From 2002 to 2013, 2(1) JAMA Cardiology 56-65 (2017).

[142] Sources from journalism include Jon Brown, Medical Textbook Strips Gender Dysphoria Definition after Being Cited by Florida, Fox News, May 8, 2022, at 8 https://www.foxnews.com/politics/textbook-strips-gender-dysphoria-definition-cited-florida [visited July 3, 2022; Lawrence S. Mayer and Paul McHugh, Sexuality and Gender: Finding from the Biological, Psychological, and Social Science, The New Atlantis (Fall 2016), https://www.thenewatlantis.com/wp-content/uploads/legacy-pdfs/20160819_TNA50SexualityandGender.pdf[visited July 3, 2022]. The citation to the student blog is Hong Phuong Nhi Le, Eminence-Based Medicine vs. Evidence-Based Medicine, Students 4 Best Evidence [blog], https://s4be.cochrane.org/blog/2016/01/12/eminence-based-medicine-vs-evidence-based-medicine/#:~:text=What%20is%20eminence-based%20medicine [visited July 3, 2022]. The website is SEGM.org, which we discuss in the text in SectionII.B and Section III.A. Citations to letters and opinion pieces include, inter alia, Andre van Mol, et al.,Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020); Michael Laidlaw, et al., The Right to Best Care for ChildrenDoes Not Include the Right to Medical Transition, 19(2) Am. J. Bioethics 75 -77 (2019); Michael Laidlaw, et al., Letter to the Editor: "Endocrine Treatment of Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Prace Guideline," 104(3) J. C linical Endocrinology and Metabolism 686-687 (2018); Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765 -766 (2020).

For example, the June 2 report attacks a 2015 study by Costa et al., claiming that the study design is flawed because it did not include a control group of adolescents without gender dysphoria.[143] This point is simply incorrect. The Costa study was designed to measure the impact of puberty blockers on gender dysphoria. To do so, the authors validly compared outcomes in teens with dysphoria who received treatment with blockers and those who did not. They were able to do this ethically because the control group of teens (who received psychotherapy but not puberty blockers) were not yet eligible for blockers or were eligible but chose to delay or forgo blockers. The study found that puberty suppression was associated with improvements in psychosocial functioning.

The Costa study is, despite the June 2 Report's claims, a solid methodology. In the context of this study, adding a third "control group" of teens without gender dysphoria would serve no scientific purpose. Further, the June 2 Report also criticizes Costa for "rel[ying] heavily on self-assessments."[144] But this is a wildly off-base criticism. Costa et al. measure psychosocial functioning using a widely-used and accepted instrument, the Children's Global Assessment Scale. Psychological research typically relies on such assessments, which are carefully constructed and psychometrically validated. This is one example of the June 2 Report's poor understanding of research in psychology and medicine.

In addition to these glaring errors, the June 2 Report's criticism of Costa makes an even more fundamental error: the June 2 report levels baseless criticisms at a single study *and fails to acknowledge that the weight of the literature as a whole strongly supports the same results that Costa et al. report*. Scientific knowledge is, importantly, cumulative. It is thus entirely misleading – and unscientific – to dismiss the effectiveness of puberty blockers by criticizing studies in isolation. Put simply, the June 2 Report fails to acknowledge the number of solid studies that all find that puberty blockers are effective.[145] Indeed, at least 16 studies show that puberty blockers and hormones benefit patients with gender dysphoria, and the benefits have been documented across study designs, including retrospective report, cross sectional, longitudinal, and qualitative studies.[146]

To take another example, the June 2 Report grossly misleads the reader in its discussion of a study by Chen et al. in 2020.[147] The report cherry-picks quotes from Chen et al. to the effect

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[143] June 2 Report, p. 15 ("Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control"). The Costa study is Rosalia Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 (11) J. Sexual Medicine P2206-2214 (2015) (hereinafter, "Costa et al. (2015)").
[144] Id.
[145] See Luke R. Allen, et al., Well-Being and Suicidality Among Transgender Youth after Gender-Affirming Hormones, 7(3) Clinical Practice in Pediatric Psychology 302-11 (2019); Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70(4) J. Adolescent Health 643-649 (2022); Jack L. Turban, et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020); Maureen D. Connolly, et al., The Mental Health of Transgender Youth: Advances in Understanding, 59(5) J. Adolescent Health 489-95 (2016); Gemma L. Witcomb et al., Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services, J. Affective Disorders (2018).
[146] For citations, see Boulware et al., supra note 27, at n. 43.
[147] Diane Chen, et al., Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Puberty Suppression in Transgender Youth, Transgender Health 246-257 (2020).

that "the effects of pubertal suppression warrant further study" and the "full consequences of suppressing endogenous puberty are not yet understood."[148]

These criticisms are misapplied, because the Chen article is not a substantive study of the effects of puberty blockers. It is, instead, a consensus parameter, which is an article that uses a structured methodology to consult experts to develop a research agenda for future studies. It is expected that the Chen piece would focus on what is not yet known, or what is not completely known, because it is attempting to identify research topics and approaches. Notably, and contrary to the June 2 Report's claims, Chen et al. recognize that existing evidence suggests that puberty blockers improve mental health functioning.

More generally, the June 2 Report's misleading characterization of Chen et al. reflects a basic lack of knowledge about scientific research. All research is flawed, including all RCTs: there simply is no perfect study in any area of medicine. The task of the scientist is to be rigorous in assessing what we know and to work to improve knowledge, incrementally, by conducting additional studies that build on earlier work. Thus, it is commonplace for authors to conclude medical research studies by calling for further research. Chen et al's statements are not indictments of puberty blockers – they are conventional acknowledgments of the value of further study that drives scientific inquiry and innovation.

The June 2 Report also contains a misleading account of the study by DeSanctis et al. The DeSanctis article reviews the literature on the use of puberty blockers (GnRHa's) for children diagnosed with central precocious puberty. De Sanctis finds that blockers are generally "safe and well-tolerated in children and adolescents" and that most drug reactions were mild. [149] The June 2 Report misleadingly and without foundation cites the De Sanctis piece as "[raising] questions about whether off-label use to treat a psychological condition [gender dysphoria] is worth the risks."[150] This attribution is bizarre, because De Sanctis et al. actually *support* the use of puberty blockers (by finding them safe and with only rare side effects) and do not offer any evidence at all to suggest that the risks are higher in the treatment of gender dysphoria.

As a final example, the June 2 Report criticizes a 2019 preliminary study by Kuper et al. without acknowledging the existence of a 2020 study by Kuper et al.[151] The earlier study presented data on the mental health of adolescents when initially presenting for care; only the later study presented full data that demonstrated the benefit of treatment.

C. The June 2 Report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact,

[148] June 2 Report, p. 15.
[149] Vincenzo De Sanctis, et al., Long-Term Effects and Significant Adverse Drug Reactions (ADRs)Associated with the Use of Gonadotropin-Releasing Hormone Analogs (GnRHa) for Central Precocious Puberty: a Brief Review of Literature, 90(3) Acta Biomed. 345-359 (2019).
[150] June 2 Report, p. 16.
[151] June 2 Report, p. 16. The earlier Kuper et al. study is Laura E. Kuper et al., Baseline Mental Health and Psychosocial Functioning of Transgender Adolescents Seeking Gender-Affirming Hormone Therapy, 40(8) J. Dev. Behav. Pediatr. 589-596 (2019). The later study is Laura E. Kuper et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

> off-label use, when supported by scientific evidence, as is the case here, is extremely common in medical practice and especially in pediatrics.

The June 2 Report repeatedly notes that the FDA has not approved the use of puberty blockers and hormones for the treatment of gender dysphoria in minors.[152] The report infers that lack of FDA approval renders a treatment unauthorized and experimental, but this is false.

Once again, the June 2 Report is (mis)using technical language in a way that is likely confusing to non-experts. The term "off-label" has a very specific meaning: a drug is off-label if the FDA has not specifically approved a particular medication for a particular use in a specific population. The off-label use of medications for children is quite common and often necessary, because an "overwhelming number of drugs" have no FDA-approved instructions for use in pediatric patients.[153]

The lack of FDA approval does not imply that the use of medications should be restricted. There is a consensus in the medical community that off-label use reflects a product of burdensome and expensive regulatory processes. Pharmaceutical companies often lack financial incentives to support research required for FDA approval for specific use in children.[154]

The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs:

> The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, *the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use.* Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient.[155]

Off-label use is so common in pediatrics that off-label drugs are prescribed in 20% of patient visits.[156] Combined hormonal contraceptives or progesterone-only contraceptive methods, which are approved on-label for contraception, are also used off-label to treat heavy menstrual bleeding, which could be due to a bleeding disorder, a delay in normal pubertal maturity or variety of other conditions; they are also used off-label for premenstrual dysphoria disorder and polycystic ovarian syndrome.

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[152] June 2 Report, pp. 8, 14, 15, 19.
[153] Boulware et al, supra note 27, quoting Kathleen A. Neville, et al., American Academy of Pediatrics Committee on Drugs, Off-label use of drugs in children, 133(3) Pediatrics 563-7 (2014) ("AAP Committee on Drugs").
[154] AAP Committee on Drugs (2014), supra note 66.
[155] Id. (emphasis added). See also Lenneke Schrier, et al., Off-label Use of Medicines in Neonates, Infants, Children, and Adolescents: a Joint Policy Statement by the European Academy of Paediatrics and the EuropeanSociety for Developmental Perinatal and Pediatric Pharmacology , 179(5) Eur. J. Pediatr 839-845 (2020).
[156] Diya Hoon, et al., Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015, 144(4) Pediatrics 1-10 (2019) (emphasis added).

A host of familiar examples provide illustrations of day-to-day, off-label use in pediatrics.[157] The use of steroids for croup is a life-saving treatment that is off-label. The medication helps toddlers get through severe, potentially airway-obstructing illnesses safely. Ondansetron (Zofran) is used off-label for nausea and vomiting to prevent fluid loss, as children are particularly vulnerable to severe dehydration.

Off-label use is also common in pediatric compassionate care, and frequently the on-label use is very different from the off-label use. Gabapentin, for example, is used on-label for the treatment of seizures but used off-label for neuropathic or mixed pain. Ketamine and fentanyl are used on-label in anesthesia but off-label for pain relief, for example, to manage chronic pain in palliative care and in patients with cancer.

In neonatal medicine, off-label medications are routinely used to treat the smallest and most fragile babies. Caffeine is used off-label to treat apnea (i.e., idiopathic respiratory arrest) of prematurity and phenobarbital is used off-label to treat neonatal seizures. More routinely, in general pediatric care, pantoprazole is a proton pump inhibitor (PPI) used to treat acid reflux. It is used off-label in neonates with gastroesophageal reflux disease who do not respond to traditional first-line treatments. It is used successfully to help infants gain adequate weight in the first four to six months of life if they do not respond to using different types of bottles, slow flow nipples, or more frequent and lower volume feedings.

In addiction medicine, routine medications like supplemental nicotine patches are off-label; they are not approved for use in those younger than 18 but are used successfully in vaping/smoking cessation, so much so that the AAP has issued guidelines on how to use and dose them. Buproprion is used on-label as an antidepressant and off-label for smoking cessation. Buprenorphine (suboxone) is used on-label in those 16 or older with opioid use disorder but used off-label in those who are younger; this medication prevents overdose death and allows those struggling with addiction to safely recover.

In psychiatry, some of the most commonly-prescribed medications for youth are off label. For example, selective serotonin reuptake inhibitors (SSRIs) are used to treat major depressive disorder and generalized anxiety in adolescents and have been shown to be effective, even though several of these ncluding sertraline and escitalopram) are off-label.[158] Other common examples include clonidine, which is FDA-approved for attention deficit hyperactivity disorder (ADHD) but is also used off-label for anxiety, insomnia, and post-traumatic stress disorder (PTSD).[159]

Finally, the June 2 Report also notes that testosterone is a controlled substance and is subject to risk of abuse, but, once again, this is misleading. The inclusion of testosterone on the schedule of controlled substances reflects the misuse of the drug by some individuals and

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[157] These examples are drawn from the list of off-label uses in AAP Committee on Drugs (2014) and reflect our clinical experience in major hospitals and clinics.
[158] For AACAP guidelines, see Boris Birmaherand David Brent, Practice Parameter for the Assessment and treatment of Children and Adolescents with Depressive Disorders, 46(110 J. Am. Acad. Child and Adolescent Psychiatry P1503-1526 (2007).
[159] Rama Yasaei and abdolreza Saadabadi, Clonidine, National L ibrary of Medicine (2022), at https://www.ncbi.nlm.nih.gov/books/NBK459124/[visited July 4, 2022].

communities (e.g., weight lifters and athletes who may use the drug to build muscle). The classification does not in any way imply that physicians should not dispense the drug if medically necessary. No special license is necessary for prescribing the medication, which is routinely prescribed to cisgender men with testosterone deficiency as well as to transgender men.

D. The June 2 Report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The June 2 Report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity. Below, we analyze two related claims made in the report and show why both are refuted by sound evidence.

First, the report claims that "the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex."[160] This is false. We have refuted this claim in detail in prior work (addressing similar claims made to support medical treatment bans in Texas and Alabama). The key point is that *adolescents with gender dysphoria rarely find that their dysphoria resolves without treatment.*[161] Because medical treatment for gender dysphoria begins only in adolescence, and only if medically necessary for gender dysphoria, medical treatment is thus provided only to a group known to be quite stable in their gender identity.

The authoritative WPATH and Endocrine Society clinical practice guidelines contain measures to ensure that medical treatment is administered only when medically necessary.[162] As part of the process of diagnosis and treatment, clinicians take care to explain to the youth and their parents the risks and the benefits of medical treatment as well as the risks and benefits of no medical interventions.

Second, the June 2 report claims, without citation, that "roughly 8% [of transgender people] decide to return to their natal sex" for reasons ranging "from treatment side effects to more self-exploration that provided insight on individuals' gender dysphoria.[163] The 8% figure is not large, but it is nevertheless an overstatement of the percentages found in the scientific literature: solid studies show very low percentages of regret (typically under 1%) among transgender people who receive medical treatment for gender dysphoria.

The June 2 report offers as general evidence for its claims about regret only a 2021 study by Littman.[164] But the Littman study cannot establish how prevalent it is for transgender individuals to reject their transgender identity. Indeed, the Littman study does not even purport

[160] June 2 Report, p. 14.
[161] Boulware et al., supra note 27, at 17-19.
[162] WPATH (2012) and Endocrine Society (201 7), supra note 5.
[163] Id.
[164] Lisa Littman, Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners, 50 Archives of Sexual Behavior 3353369 (2021).

to show the percentage of transgender people who "detransition." Instead, it simply asked 100 people who self-identified as "detransitioners" about their reasons. Using Littman's study as evidence of widespread regret is akin to saying that giant pandas (an endangered species) are common because, if we search, we can find 100 of them.

Furthermore, the Littman study used a biased sampling and survey methodology: survey was anonymous; its participants were solicited from (among other venues) anti-transgender social media groups.

Finally, the June 2 Report makes a flagrant error in conflating "detransition" with "regret."[165] In addition, the Littman study is unscientific in describing a likely very diverse group of people as "detransitioners." She defines detransition as "discontinuing medications, having surgery to reverse the effects of transition, or both." Littman's definition is highly misleading, because transgender people may have many reasons to discontinue medication. One might continue to live socially in a gender role that is not the one assigned at birth and yet, by Littman's criteria, be counted as a "detransitioner." In our clinical practice, we have seen youth who discontinued hormone therapy because the effects had addressed their dysphoria; these patients were nonbinary, but Littman's method would mistakenly count them as "detransitioners."

By contrast, the June 2 report disregards a very large and far more nuanced and important 2021 study by Turban et al., which shows that transgender people who do return to live as the sex assigned at birth may not permanently do so and are, by their own report, influenced largely by "external factors, such as pressure from family, nonaffirming school environments, and sexual assault."[166] The study found that only a minority of survey participants "reported that detransition was due to internal factors, including psychological reasons, uncertainty about gender identity, and fluctuations in gender identity." Indeed, as the authors note, these psychological experiences "*did not necessarily reflect regret* regarding past gender affirmation, and were presumably temporary, as all of these respondents subsequently identified as transgender/gender diverse, an eligibility requirement for study participation."[167]

The June 2 Report also ignores a recent study, Olson et al. (2022), who find that after an average of 5 years of social transition, only 2.5% of youth identified as cisgender.[168]

Studies that actually focus on regret consistently find that transgender people only rarely regret their medical treatments.[169] For example, Bustos et al. (2021) found regret expressed by one

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[165] See generally Jack L. Turban, et al., Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis, 8(4) LGBT Health 273-280 (2021) (noting that "the term 'detransition' has at times been conflated with regret, particularly with regard to medical and surgical affirmation").
[166] Id.
[167] Id.
[168] Kristina R. Olson, et al., Gender Identity Five Years After Social Transition, Pediatrics (preprint, May 2022) .
[169] Valeria P. Bustos, et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9(3) Plastic and Reconstructive Surgery- Global Open e3477 (2021); Sara Danker, et al., Abstract: A Survey Study of Surgeons' Experience with Regret and/or Reversal of Gender-Confirmation Surgeries, 6(9 Supp.) Plastic and Reconstructive Surgery 189 (2018); Chantal M. Wiepjes, et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15(4) J. Sex Med. 582-590 (2018); see also Yolanda L.S. Smith, et al., Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals, 35(1) Psychological Medicine 89-99 (2005).

percent or fewer of transgender patients who underwent gender-affirming surgery, and Danker et al. (2018) report a rate of far less than 1%, as do Wiepjes et al. (2015).[170]

> E. The June 2 Report repeats discredited claims that "social contagion" is leading teens to become transgender. The issue, although sensationalized in the June 2 Report, is ultimately irrelevant to medical treatment, which is provided only after a multidisciplinary assessment and after a finding that gender dysphoria is persistent and medical treatment is warranted.

The June 2 Report claims that "social factors (e.g., peer influences and media) may be contributing factors to gender dysphoria,"[171] citing as evidence a single, discredited study by Littman. We have addressed this study at length in other work and note that

> WPATH, among other authorities, has taken a skeptical view of Littman's claim, and the study has been criticized for serious methodological errors, including the use of parent reports instead of clinical data and the recruitment of its sample of parents from anti-transgender websites. The journal of publication required an extensive correction of the original Littman article because of its misstatements. Such a correction in reputable, peer-reviewed academic journals is taken only when a panel of experts, in retrospect, came to recognize the methodological flaws of the original study and concluded that it would be unscientific to allow the originally published findings to stand."[172]

Littman's sensationalist hypothesis has been widely covered in the press, but no clinical studies have found that rapid-onset gender dysphoria exists. Further, no professional organization has recognized "rapid-onset gender dysphoria" as a distinct clinical condition or diagnosis.

Most recently, an April 2022 study of 173 youth presenting at Canadian gender clinics *found no evidence of rapid-onset dysphoria or social contagion.* The researchers posited that if "rapid onset" gender dysphoria were a real phenomenon, then teens who had more recently begun identifying as transgender would (per the Littman hypothesis) also be more likely to report online support and engagement in their gender identity. They might also (per Littman's hypothesis) be more likely to struggle with mental health concerns**.**

An April 2022 study of 173 youth found no such correlations, strongly undercutting the "rapid-onset" hypothesis endorsed by the June 2 report. The researchers controlled for age and sex assigned at birth and looked for correlations with recent gender knowledge (defined as less than one to two years having passed since "you realized your gender was different from what other people called you"). Recent gender knowledge was *not* significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, or self-harm. Nor was it associated with having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents.[173]

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[170] Id.
[171] June 2 Report, p. 12.
[172] Boulware et al., supra note 27, at 20-21 (internal citations omitted).
[173] Greta R. Bauer, et al., 243 J. Pediatrics 224 -227 (2022).

Data do substantiate that younger people today are more likely to identify as transgender than are older people, but this does not substantiate the idea of social contagion. The increase may be due to the increasing social acceptance of gender diversity (i.e., older people grew up in a more transphobic social environment). In fact, adolescent presentation of transgender identity is often observed and should not be pathologized. In the largest U.S. sample of transgender adults, over half reported first starting to realize that they were transgender in adolescence (57% ages 11-20) and roughly half (47%) started to disclose their identity during this time frame.[174]

Further, the data do not show a massive wave of transgender identity even among teens. A 2022 study by the Williams Institute found that, using an expansive definition of "transgender," about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people.[175] This is not a large percentage or a large absolute number.

Underlying the June 2 Report's claim about social contagion is a set of imagined stereotypes – that teenagers do not known their own gender identity and readily change their gender identity based on peer influence and social media. But these stereotypes contradict the scientific understanding of gender identity formation. Studies of so-called "conversion" or "reparative" therapy, for example, finds that transgender identity is highly resistant to change even in the face of concerted efforts by medical authorities versed in psychological methods. Studies find that conversion therapy is ineffective in altering gender identity and is psychologically damaging.[176]

> F. The June 2 Report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by scientific evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

The June 2 Report speculates that because "a high proportion" of youth receiving medical care for gender dysphoria also have a behavioral health disorder, "available research raises questions as to whether the [individuals'] distress is secondary to pre-existing behavioral health disorders and not gender dysphoria."[177] In simpler terms, *the June 2 Report speculates that perhaps gender dysphoria is not real but is, rather, an imagined by-product of underlying mental illness.* A close examination shows that this claim has no foundation in science; it rests on unexamined and harmful stereotypes and unaccountably dismisses the scientific knowledge and clinical skill of child and adolescent psychologists and psychiatrists.

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[174] Sandy E. James, et al., The Report of the 2015 U.S. Transgender Survey, National Center for Transgender Equality (2015).
[175] Jody L. Herman, et al., How Many Adults and Youth Identify as Transgender in the United States?, U.C.L.A. School of Law, Williams Institute (2022).
[176] A survey of the scientific literature by the U.S. Department of Health and Human Services finds that "no ne of the existing research supports the premise that mental or behavioral health interventions can alter gender identity or sexual orientation." Substance Abuse and Mental Health Services Administration, Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth, U.S. Department of Health and Human Services, HHS Publication No. (SMA) 15-4928 (2015), p. 1.
[177] June 2 Report, p. 6.

First, the June 2 Report implicitly posits a causal hypothesis that behavioral health disorders cause gender dysphoria. This hypothesis is entirely devoid of scientific evidence. Indeed, the scientific evidence strongly suggests that the direction of causation runs the other way. It is well-established that being transgender leads to mental health concerns because of the social stress and discrimination of being transgender in a society that is strongly oriented to cisgender identity and disapproving of transgender identity.[178] In our society, transgender individuals experience a great deal of discrimination, hostility, and physical violence. Quite simply, it is unsafe to be transgender in this current hostile climate.[179] Accumulation of existential fear and threatening experiences can manifest as physical and mental conditions. Thus, one would expect – and studies confirm – that transgender people, on average, have worse physical and mental health than cisgender people.

Although the effects of gender minority stress are well-known, the June 2 Report makes no mention of the literature. Instead, it indulges in speculation based, apparently, on the stereotyping of transgender people as confused and dysfunctional. The June 2 Report posits that individuals with mental health concerns cannot be trusted to understand their own gender identity. This is a highly prejudicial stance and one that disregards the key role of psychologists and psychiatrists, who have developed sensitive and effective approaches to treating adolescents with gender dysphoria and mental health concerns.[180]

Second, the co-occurrence of psychological distress among individuals with gender dysphoria provides no reason for denying care. Any population of individuals – cisgender or transgender – will include some with mental health concerns, and the WPATH and Endocrine Society guidelines recognize that there is a higher prevalence of anxiety, depression and post-traumatic stress disorder among transgender youth than among cisgender youth. In response, the guidelines set out practices that include a careful psychological assessment of each adolescent as part of the process for determining whether medical treatment for gender dysphoria is appropriate and likely to have benefits that outweigh risks.

The Endocrine Society guidelines specifically recommend that mental health professionals should be able to diagnose gender dysphoria and distinguish it from other "conditions that have similar features (*e.g.*, body dysmorphic disorder)." In addition, the mental health provider should be prepared to diagnose psychiatric conditions, provide or refer for treatment, and to "psychosocially assess the person's understanding, mental health, and social conditions that can

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[178] Rylan J. Testa, et al., Development of the Gender Minority Stress and Resilience Measure, 2(1) Psychology of Sexual Orientation and Gender Diversity 65-77 (2015); Rylan J. Testa, et al., Suicidal Ideation in Transgender People: Gender Minority Stress and Interpersonal Theory Factors, 126(1) J. Abnormal Psychology 125-36 (2017); Alexandrai M. Delozier, et al., Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review from a Minority Stress Framework, 45(8) J. Pediatric Psychology 842-847 (2020); Jessica Hunter, et al., Gender Minority Stress in Trans and Gender Diverse Adolescents and Young People, 26(4) Clinical Child Psychology and Psychiatry 1182-1195 (2021).

[179] See, e.g., Rebecca L. Stotzer, Violence Against Transgender People: A Review of United States Data, 14(3) Aggression and Violent Behavior 170-179 (2009).

[180] See John F. Strang, et al., Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents, 47(1) J. Clinical Child & Adolescent Psychology 105-115 (2016).

impact gender-affirming hormone therapy."[181] In our clinical practice, we also ensure that youth and their caregivers have the information and support necessary to fully understand the risks, benefits, and outcomes of treatment. That is, we not only provide assessment but also fill in any gaps in understanding and support the decision-making process.

Our experience in clinical practice reflects these guidelines. Any consultation for medical treatment for gender dysphoria includes a mental health assessment. Further, the treatment plan for each adolescent is then individualized to reflect the risks and benefits of treatment and the risks and benefits of no treatment. Consistent with the WPATH guidelines, as clinicians, we ensure that the mental health concerns are not interfering with our ability to assess gender dysphoria and youth assent to treatment.

Third, the June 2 Report implicitly claims that any mental health disorder impairs a minor's ability to provide informed assent and, somehow, also invalidates the informed consent of their guardian. Experts in child and adolescent psychiatry, child psychology, and adolescent medicine have established that youth can make complex medical decisions. Further, the literature specifically demonstrates that transgender youth with co-occurring mental health conditions can competently participate in decision-making.[182] With guidance from mental health providers, parents, and physicians, teens can be part of a decision process that helps them explore their identity and make nuanced decisions about the benefits and risks of medical treatment.[183] Indeed, these processes of exploration and decision-making are central goals of, and central tasks for, trained mental health providers who work with teens.

> G. The June 2 Report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies, which show that medical care is more effective than psychotherapy alone.

The June 2 Report argues, without scientific evidence, that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy, an approach that it mistakenly terms "watchful waiting."[184]

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[181] Endocrine Society (2017), supra note 5.
[182] Lieke J. Vrouenraets, et al., Assessing Medical Decision-Making Competence in Transgender Youth, 148(6) Pediatrics e2020049643 (2021).
[183] Beth A. Clark and Alice Virani, "This wasn't a Split-Second Decision": An Empirical Ethical Analysis of Transgender Youth Capacity, Rights, and Authority to Consent to Hormone Therapy, 18 J. Bioethical Inquiry 151-164(2021); Vrouenrats, et al., supra note 95; Megan S. O'Brien, Critical Issues for Psychiatric Medication Shared Decision Making with Youth and Families, 92(3) Families in Society 310-316 (2011); Mary Ann McCabe, Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations 21(4) J. Pediatric Psychology 505-516 (1996).
[184] For example, at p. 12, the June 2 Report asks, "[S]hould conventional behavioral health services be utilized without proposing treatments that pose irreversible effects [i.e., drug therapies]? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects {i.e., the watchful waiting approach)?" At p. 20, the June 2 Report misuses the term "watchful waiting" to describe the denial of medical care to adolescents with gender dysphoria, and the report miscites its own purported expert report. The Cantor document discusses "watchful waiting" meaning the denial of social transition to prepubertal children, not the denial of medical treatment to adolescents. Cantor document, p. 10-11.

The report offers no actual evidence for this denial of standard medical care. Its recommendation rests, instead, on an unfounded and mistaken criticism of the existing literature. The Cantor document, attached to the AHCA report as Appendix C, states that several studies "successfully identified evidence of [mental health] improvement [due to medical treatment for gender dysphoria], *but because patients received psychotherapy along with medical services, which of those treatments caused the improvement is unknowable.*"[185]

This statement is false. Medical treatment for gender dysphoria has been shown to lead to positive effects on mental health that are not associated with psychotherapy alone. Costa et al. in 2015 found that puberty blockers improve psychosocial functioning in teens with gender dysphoria, compared to teens who receive psychotherapy but not blockers.[186] Costa's study ewas designed to include a control group of teens with gender dysphoria who did not receive blockers.

In a 2022 study, Tordoff et al find that puberty blockers and hormone therapy are associated with significant improvements in depression and suicidality in a population of transgender and nonbinary youths aged 13 to 20.[187] The authors showed the independent effects of medications such as puberty blockers and hormones on depression, anxiety, and gender dysphoria. They controlled for temporal trends and other confounding factors, expressly including whether the teen received "ongoing mental health therapy other than for the purpose of a mental health assessment to receive a gender dysphoria diagnosis."[188] Put simply, Tordoff et al. clearly found that youth with gender dysphoria reported better outcomes if they received puberty blockers, even after controlling for the effects of psychotherapy.

Similarly, in a 2020 study, Laura Kuper et al. found that gender-affirming hormone therapy made a large improvement in adolescents' body-related distress and led to small to moderate improvement in symptoms of depression and anxiety.[189] Kuper et al. specifically collected data on psychotherapy and the use of psychiatric medications and expressly controlled for both. Thus, Kuper et al.'s study shows that hormone treatment for gender dysphoria is effective above and beyond the benefits of psychotherapy and psychiatric medications.

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[185] Cantor document, p. 13.
[186] Costa et al., supra note 56.
[187] Diana M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5(2) JAMA Network Open e220978 (2022).
[188] Id.
[189] Laura E. Kuper, et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

From: FL-Rules@dos.state.fl.us
Sent: Thursday, July 7, 2022 1:43 PM EDT
To: Cole.Giering@ahca.myflorida.com
Subject: One-time User Comment From FLRules.com

FLRules.com one-time comment:

Name: Scott VanDeman
Email: svandeman@fcaap.org
Title: Comments from American Academy of Pediatrics and Florida Chapter, American Academy of Pediatrics
Comment: July 7, 2022

Tom Wallace
Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive
Mail Stop #8
Tallahassee, FL 32308

Dear Director Wallace,

The American Academy of Pediatrics (AAP), a nonprofit organization representing 67,000 pediatricians dedicated to the health, safety and well-being of all children and the Florida Chapter of American Academy of Pediatrics, Inc (FCAAP), a nonprofit organization representing more than 2,600 pediatricians committed to serving all children across the state, thank you for the opportunity to provide comments on the Florida Agency for Health Care Administration's proposed rule to prohibit gender-affirming care in the state's Medicaid program.

We write to express our grave concerns with the proposed rule. Denying evidence-based, medically necessary standards of care to transgender adolescents constitutes a broad and sweeping discriminatory action by the State of Florida and its Medicaid program.

Gender-affirming care is the widely accepted standard of care for treating transgender adolescents with gender dysphoria. Gender-affirming care is endorsed and recommended by the American Academy of Pediatrics; the Florida Chapter of the American Academy of Pediatrics, Inc; the American Medical Association; the American College of Obstetricians and Gynecologists; the American College of Physicians; the American Psychiatric Association; the American Psychological Association; the American Academy of Family Physicians; the American Academy of Child and Adolescent Psychiatry; the Endocrine Society; the Society for Adolescent Health and Medicine; the Pediatric Endocrine Society; the World Professional Association for Transgender Health (WPATH); and many more members of the medical community.

Gender-Affirming Care is the Standard of Care
Gender-affirming care is developmentally appropriate care that seeks to understand and appreciate a child's or adolescent's gender identity and experience through a safe and nonjudgmental partnership that includes general pediatricians, pediatric specialists, mental health providers, children and adolescents and their families. While gender-affirming care is irrefutably the standard of care, it must, like all other areas of medicine, be individualized to meet the needs of each and every unique patient.

WPATH and the Endocrine Society have developed well-researched and evidence-based standards of care and clinical guidelines for the care of children and adolescents with gender dysphoria. WPATH's Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7 and the Endocrine Society's Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (both are herein referenced as "standards of care") are in fact the gold standard, contrary to the State of

Pl. Trial Ex. 307

Florida's assertion, among the medical community for caring for children and adolescents with gender dysphoria.

For a model of care to be considered the standard of care for a specific diagnosis, the care must be "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals." The State of Florida's attempt to argue that gender-affirming care is not the standard of care, as referenced in its Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria report and its "Florida Fact-Checked" version of the HHS Office of Population Affairs Guidance on gender-affirming care, is entirely inconsistent with the well-recognized and established definition of standard of care, and represents a purposeful mischaracterization of available evidence as well as the position of the medical community.

Instead of supporting the standard of care for transgender adolescents, the state is seeking to rely only on "watchful waiting." This outdated model is based on long-refuted binary notions of gender and assumes without evidence that gender identity becomes fixed at a certain age and will result in direct harm to gender dysphoric children and adolescents who are denied access to well-evidenced multidisciplinary care. Notably, "watchful waiting" is based on studies with flawed methodology, validity concerns, and limited follow-up of transgender adolescents. Thus, "watchful waiting" is not recommended by any major medical association in the United States.

Gender Dysphoria
Gender dysphoria is a formal diagnosis under The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) in which there is a pronounced incongruence between someone's gender identity or expression and sex assigned at birth. For the diagnosis, the patient must exhibit 2 of the following for at least 6 months:
? A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
? A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
? A strong desire for the primary and/or secondary sex characteristics of the other gender
? A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
? A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
? A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)
In an apparent attempt to undermine the validity of the diagnosis of gender dysphoria, the state, under "Etiology of Gender Dysphoria," implies that mental and physical health conditions are the primary cause of gender dysphoria and that psychological support is all that is needed to provide care for gender dysphoric youth. However, the preponderance of the evidence indicates that gender dysphoria is indeed a primary diagnosis in which mental health issues are often exacerbated by lack of access to appropriate gender affirming care. The state disqualifies its own arguments by stating: "At the moment, none of these studies provides a definitive cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative." To be clear, there is no evidence that mental or physical health conditions cause gender dysphoria. As such, mischaracterizing the diagnosis in an effort to prohibit gender-affirming care is disingenuous at best and would result in direct harm to transgender children and adolescents.

Included in the state's document is the suggestion that mental health care should be the first line of care for youth diagnosed with gender dysphoria. On this, we agree. In fact, the evidence-based standards of care for gender-dysphoria, as referenced above, recommend mental health evaluation and care as the first step for affected children and adolescents. Indeed, research demonstrates that transgender children and adolescents experience stigma and discrimination, which adversely affects their mental health. Children and adolescents diagnosed with gender dysphoria often have to hide their gender identities to avoid bullying and harassment and face greater risks of homelessness, physical violence in the home and in the community, and substance use. However, the state conflates the association of mental health diagnoses, trauma, and attachment issues with causality for gender dysphoria in an effort to discredit the primary diagnosis. In reality, the mental health issues faced by those with gender dysphoria are often the direct result of a lack of access to care or not being supported in their gender identity.

In further attempting to undermine the well-established diagnosis of gender dysphoria, the state seeks to incorporate

the concept of "rapid onset gender dysphoria." The manuscript from which the term "rapid onset gender dysphoria" originates has been widely criticized. An expert review emphasized the following issues:

? "This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals."
? "…the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing."

The Coalition for the Advancement & Application of Psychological Science, which includes the American Psychiatric Association, the American Psychological Association, the Society for a Science of Clinical Psychology, the Society of Clinical Child and Adolescent Psychology, the Society of Pediatric Psychology, and many more international, national, and state psychological and psychiatric associations, published a position statement on the concept of rapid onset gender dysphoria, stating:

? …it has not been subjected to rigorous peer-review processes that are standard for clinical science. Further, there is no evidence that ROGD aligns with the lived experiences of transgender children and adolescents.
? Research on gender identity development in children and adolescents continues to evolve and these advances will likely influence diagnosis and empirically-based standards of care, as well as the legislative landscape impacting trans people's access to care and legal protections. The available research is clear that transgender people are subjected to marginalization, stigmatization, and minority stress, which have significant detrimental effects on health and well-being. Terms, such as ROGD, that further stigmatize and limit access to gender-affirming and evidence-based care violate the principles upon which CAAPS was founded and public trust in clinical science.

Mental Health Care
Under the evidence-based standards of care, mental health care is indeed the first step in the care of children and adolescents diagnosed with gender dysphoria. The evidence-based standards of care recommend that a child or adolescent diagnosed with gender dysphoria be seen and evaluated by a qualified mental health professional trained in child and adolescent developmental psychopathology, competent in diagnosing and treating the ordinary problems of children and adolescents and meeting the same competency requirements as mental health professionals working with adults. Under the evidence-based standards of care, a qualified mental health professional has a responsibility to:

? Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below).
? Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.
? Assess and treat any coexisting mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan.
? Refer adolescents for additional physical interventions (such as puberty-suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments.
? Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, & Salter, 2006 Grossman, D'Augelli, Howell, & Hubbard, 2006); Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010).

? Provide children, youth, and their families with information and referral for peer support such as support groups for parents of gender-nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).

The evidence-based standards of care clearly recommend that mental health providers who care for children and adolescents with gender dysphoria diagnose and treat any other mental health conditions the child or adolescent is experiencing. Thus, the state's implication that mental health providers are not addressing existing mental health concerns prior to beginning gender-affirming medical care is wholly inaccurate. Prior to puberty, mental health professionals, pediatricians, and other health care providers "work together to destigmatize gender variance, promote the child's self-worth, facilitate access to care, educate families, and advocate for safer community spaces where children are free to develop and explore their gender" without medical interventions.

Medical Care
The state begins its literature review on gender dysphoria and puberty suppression by attempting to argue that a majority of children and adolescents will cease showing signs of gender dysphoria and conform to their sex assigned at birth. Herein lies a distinction between prepubertal children and adolescents that the state fails to consider, or outright ignores.

In its "Florida Fact-Checked" version of the HHS Gender Affirming Care document, the state notes that "most children identifying as transgender will detransition following the onset of puberty." Additionally, in the ACHA GAPMS report, the state makes a similar argument, including "neither organization explains that a majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that puberty suppression can have side effects." By definition, a child is defined as "a young person especially between infancy and puberty," while adolescence is defined as "the period of life when a child develops into an adult: the period from puberty to maturity terminating legally at the age of majority." The key difference between children and adolescents being the onset of puberty. By referencing "children" it is "Florida Fact- Checked" document and "young adolescents" in the ACHA GAPMS report, the state erroneously conflates the 2 terms. However, the definitions of these terms are different and cannot be used interchangeably.

Furthermore, the state relies on a study that "offers data on the percentage of children who opt not to transition after experiencing gender dysphoria." Similar claims made in other states that have attempted to ban gender-affirming care have been thoroughly debunked by a recent expert review from faculty from Yale University and the University of Texas Southwestern. The report from Yale examined in detail the misrepresentation of the Steensma et al study, explaining that:

? "...the Steensma study was not designed to (and the lead author has acknowledged) does not provide a basis for calculating what percentage of prepubertal children diagnosed with gender dysphoria persist with that diagnosis into adolescence. Rather, the Steensma study was designed only to study the characteristics of those who persisted.60 Among other limitations, in Steensma (2013), former patients who opted to not participate in the study (either refused to participate or did not respond to an offer to participate) were categorized as "desisters," i.e., patients whose gender dysphoria resolved without transition or treatment. Patients can fail to respond to a study request for many reasons, including having moved away, receiving treatment elsewhere, or being uninterested in participating in a study. Thus, SEGM misuses the Steensma data by counting nonresponding patients as having "desisted" in experiencing gender dysphoria.61 Indeed, in published correspondence, Steensma emphasizes that the 2013 study should not be used to calculate the percentages of "persisters" and "desisters."62 The misrepresentation of Steensma on the SEGM website constitutes a major violation of the scientific method and the accepted conventions of research."

Some prepubertal children's diagnosis of gender dysphoria will indeed not continue in adolescence, and as such, there are no recommended medical interventions for prepubertal children. For prepubertal children, gender exploration is a natural part of child development. However, for children diagnosed with gender dysphoria persisting at the onset of puberty (adolescence), research demonstrates that gender dysphoria will continue. ; Under gender-affirming care, adolescents diagnosed with gender dysphoria, after careful and exhaustive mental health evaluation and care , may progress to gender-affirming medical care under the evidence-based standards of care.

Pubertal Blockers

Under the evidence-based standards of care, gender-affirming medical care is a highly individualized model of care. Prior to beginning gonadotrophin-releasing hormone agonists (GnRH, herein referred to as puberty blockers) as a component of a multidisciplinary approach to caring for adolescents diagnosed with gender dysphoria, adolescents must meet stringent criteria under the evidence-based standards of care from WPATH, including:

? The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);
? Gender dysphoria emerged or worsened with the onset of puberty;
? Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment.
? The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."

The Endocrine Society lays out additional criteria that must be met prior to undergoing puberty blockers as a component of gender-affirming medical care:

? (the adolescent) has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
? (the adolescent) has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
? And a pediatric endocrinologist or other clinician experienced in pubertal assessment
o agrees with the indication for GnRH agonist treatment,
o has confirmed that puberty has started in the adolescent (Tanner stage =G2/B2),
o has confirmed that there are no medical contraindications to GnRH agonist treatment.

In the ACHA GAPMS report and the "Florida Fact- Checked" document, the state asserts that there is no credible evidence demonstrating puberty blockers benefit adolescents diagnosed with gender dysphoria. However, the state either unknowingly or willingly ignores the body of evidence that supports this practice. Medication to suppress puberty has been used to treat precocious puberty for decades. The identical therapeutics are also used in adolescents diagnosed with gender-dysphoria and perhaps more importantly represent a very reasonable balance of risk and benefit when considering the totality of the available data and clinical experience. The pubertal blocker phase of gender-affirming care importantly allows the patient to delay the development of secondary sex characteristics. By pausing the progression of secondary sex characteristics, adolescents are provided time to explore their gender identity, access and/or continue mental health support, and assess and define their treatment goals, in conjunction with their families.

Contrary to the state's assertion that the evidence supporting use of puberty blockers is "weak," a large body of evidence supports their use in adolescents diagnosed with gender dysphoria. For example, recent research examined 272 adolescents who were referred to a gender clinic, but had not yet began undergoing gender-affirming medical care, including puberty blockers, and 178 adolescents who had already began receiving gender-affirming care using puberty blockers with 651 cisgender adolescents. The researchers found that adolescents with gender dysphoria had worse psychological health compared with their cisgender adolescent peers and that after receiving puberty blockers as part of gender-affirming care, the adolescents with gender dysphoria had similar or better psychological health than their cisgender peers. Another recent study found that transgender adults who wanted and were able to access puberty blockers as adolescents were less likely to have lifetime suicidal ideation compared to transgender adults who were not able to access puberty suppression medication as adolescents. In a 2-year follow-up study, researchers found that the use of puberty blockers led to improvements in overall functioning and decreased instances of depression.

The state further asserts that "puberty suppression causes side effects, some of which have the potential to be permanent." However, experts point out that "recent studies suggest that puberty-blocking medication has

negligible or small effects on bone development in adolescents, and any negative effects are temporary and reversible. The most recent studies show that puberty-blocking drug therapy either has no effect on bone mineral density (BMD), a proxy measure of bone strength, or is associated with a very small decrease." Overall, the studies that have examined the use of puberty blockers, as a component of gender-affirming care, demonstrate that the use of these medications is evidence-based and provides for an appropriate risk/benefit ratio for adolescents diagnosed with gender dysphoria.

In addition, the state fixates on the argument that puberty blockers are used off-label, not approved by the Federal Drug Administration (FDA), and that no randomized clinical trials (RCT) have been completed on the use of puberty blockers to treat gender dysphoria. These arguments lack any basis. First, in pediatric medicine, "the purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." The use of off-label medication in pediatric medicine is supported by clinical evidence and data. In suggesting that puberty blockers cannot be used to treat gender dysphoria simply because they have not been approved by the FDA for such purposes, the state fails to understand the relationship between the FDA and the practice of medicine:

? Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.

The use of off-label medication in pediatric medicine is not experimental, nor does it constitute anything other than the practice of evidence-based medicine. Off-label medication use for pediatric patients is commonplace and there is no basis to prohibit puberty blockers because of their off-label use in pediatrics.

The state's argument that puberty blockers have not undergone RCTs and therefore should be disqualified for use treating adolescents diagnosed with gender dysphoria is also severely flawed. As explained by Armand H. Antommaria, MD, PhD, FAAP, HEC-C, Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center:

? …it may, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.

Furthermore, a group of leading bioethicists echo Dr Antommaria's explanation: "Randomized control trials also are only ethical when there is clinical "equipoise," which means they are only appropriate when there is genuine uncertainty about whether the intervention will be more effective than the control." There is no uncertainty about the use of puberty blockers to treat adolescents diagnosed with gender dysphoria -- the evidence fully supports this intervention as a component of gender-affirming care. Studies other than RCTs are, in fact, utilized regularly in the practice of medicine and are preferable in some instances.

Gender-Affirming Hormone Therapy
As a component of gender-affirming care, adolescents who have received extensive mental health care and puberty blockers may progress to hormone therapy. As with every component of gender-affirming care, the use of hormone therapy is a highly individualized decision, and any decisions are made in concert with the adolescent, their family, and mental health and medical care providers. Under the evidence-based standards of care for receiving hormone

therapy, the following criteria must be met:

? A qualified MHP (mental health professional) has confirmed:
o the persistence of gender dysphoria,
o any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
o the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
? And the adolescent:
o has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
o has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
? And a pediatric endocrinologist or other clinician experienced in pubertal induction:
o agrees with the indication for sex hormone treatment,
o has confirmed that there are no medical contraindications to sex hormone treatment.

The state remarks in its Fact-Checked document that it is "misleading" to state that hormone therapy is partially reversible. This is purposefully misleading. The evidence-based standards of care acknowledge that some forms of hormone therapy are reversible and that some are not reversible. Initiating hormone therapy is not a decision that is made lightly and there are stringent criteria that must be met, as referenced above. Furthermore, experts at Yale University explain that hormone therapy has a wide range of uses in adolescents:

? Estrogen and testosterone are often used off-label to treat adolescents with intersex conditions. Common hormonal medications used off-label include norethindrone, a progesterone analogue used off-label for the treatment of heavy menstrual bleeding in those with polycystic ovarian syndrome, bleeding disorder, and anovulatory bleeding of early puberty. It is also used to treat endometriosis, which is a painful inflammatory condition. Many forms of combined hormonal contraception, as well as a testosterone-blocking medication (spironolactone), are used off-label to treat acne. Other examples include clonidine, a blood pressure medication used off-label for the treatment of ADHD, migraine headaches, disorders of behavioral regulation, and insomnia; and propranolol, a blood pressure medication used off-label for the treatment of performance anxiety.

As referenced in the preceding paragraph, the off-label use of hormone therapy for adolescents diagnosed with gender dysphoria "does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient." Decision-making to initiate this form of gender-affirming care takes place at the clinical level, using the evidence-based standards of care and the best available evidence. By attempting to argue that hormone therapy is somehow more dangerous to adolescents with gender dysphoria than to cisgender adolescents undergoing to same treatment for a different medical condition, the state makes it abundantly clear that this is not about the health and well-being of adolescents; it is rather a misguided attempt to discriminate against adolescents with gender dysphoria.

In the GAPMS report, the state cites a study by Dutra et al that "examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that the use of estrogen or testosterone can increase risks for cardiovascular disease." To use this as a basis for the state's argument to prohibit gender-affirming care for adolescents diagnosed with gender dysphoria would mean that the state would need to prohibit the use of hormone therapy in Florida's population at large. Additionally, in making this argument the state fails to consider the intent of hormone therapy -- to align one's body with one's gender identity. The experts at Yale University also clarify this misrepresentation or misunderstanding:

? The medical result is that transgender individuals move toward the typical medical profile of their identified gender. And so transgender women, like cisgender women, have lower risks of cardiovascular disease than

cisgender men.111 Transgender women, like cisgender women, have a slightly higher risk of venous thromboembolism than cisgender men. In fact, transgender women have a lower risk of venous thromboembolism than cisgender women, and the overall risk is extremely low (less than 1%) for all transgender individuals, both women and men.112 The risk of venous thromboembolism in transgender women and non-pregnant cisgender women is less than the risk in pregnancy, which is the highest estrogenic physiologic state known.
? It is also critical to note that the medical impact of gender-affirming treatment is generally the same in transgender people as in cisgender people who take the same hormone medications. For example, physicians commonly prescribe hormonal contraceptives containing ethinyl estradiol (a synthetic estrogen) to adolescents for reasons including birth control, management of irregular or painful menstrual periods, and acne. In other words, similar doses of exogenous sex hormones are commonly administered to cisgender individuals for a host of reasons and are well tolerated.

Research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents diagnosed with gender dysphoria. A recent study in the Journal of Adolescent Health examined data from transgender or nonbinary adolescents and young adults between 13-24 and found that the provision of hormone therapy in those under 18 resulted in lower levels of depression and suicide attempts compared to adolescents who were unable to access hormone therapy. Another recent study demonstrated that the provision of puberty blockers and hormone therapy reduced depression and suicidality over the course of 1 year.

Additionally, the evidence cited in the evidence-based standards of care reinforces the sound basis for the provision of hormone therapy in adolescents diagnosed with gender dysphoria. Under the evidence-based standards of care, there are specific criteria for gender-affirming surgical interventions. The state's focus on gender-affirming surgery and its attempt to classify it as common is a blatant misrepresentation intended to politicize the issue and cast doubt on the evidence-based standards of care.

Risks
Unlike the state's assertion on its "Florida Fact-Checked" document that "no reliable evidence shows that gender dysphoria significantly increases the risk of suicide," there is in fact evidence to support this. In a study of more than 1,000 transgender adolescents, transgender adolescents had higher odds of all suicide outcomes compared to cisgender adolescents, and were at greater risk for suicidal ideations and attempts compared to their cisgender peers. Additionally, in the first large scale (N = 120,670) study examining the relationship between transgender adolescents and suicide, the authors found that between 30-51% of transgender adolescents reported engaging in suicidal behavior, compared to between 10-18% of their cisgender peers.

As noted in the earlier section on mental health, adolescents with gender dysphoria face increased bullying, discrimination, harassment, and a lack of social acceptance. To add to these daily, ongoing issues, adolescents with gender dysphoria are at greater risk for suicide and other mental health conditions. Curiously, the State of Florida appears to agree that transgender adolescents (and other LGBTQ adolescents) face more serious mental health concerns than their cisgender peers, as it maintains a web site, Youth Suicide Prevention under the FL Department of Health, explaining the protective factors and risks associated with suicide in adolescents (the state refers to this population as teens). In identifying these protective factors and risks associated with suicide in adolescents, the state readily admits that "It is important to know that some youths experience an increased amount of risk. Youths are those who identify as LGBTQ, American Indian/Alaska Native, youth in the child welfare and juvenile justice systems or military service members can have higher incidence of suicidal behavior." The state cannot have it both ways; it cannot argue that gender dysphoria doesn't increase the risk of suicide, as noted it its "Florida Fact-Checked" document (ignoring the evidence that patently refutes this argument), and then readily acknowledge via its youth suicide prevention web site that transgender adolescents are at increased risk of suicide.

As referenced in an earlier section of this comment letter, access to and the provision of puberty blockers and hormone therapy as part of gender-affirming care works and is the gold standard according to the medical community to alleviate mental health conditions and risks associated with gender dysphoria in adolescents.

Medicaid is a Critical Source of Health Care for Children, including Transgender Adolescents
Medicaid is a vital source of health insurance for children (for data reporting purposes below, the term "children" is inclusive of "adolescents") in Florida and across the United States. Nationally, children make up the single largest group of enrollees in Medicaid and the Children's Health Insurance Program (CHIP); more than 40 million—or 53%

of all US children—rely on Medicaid and CHIP coverage, including with special health care needs and those from low-income families. In Florida, over 2.8 million children were enrolled in Medicaid or CHIP as of February 2022. Medicaid also provides comprehensive prenatal care, enabling millions of healthy pregnancies and births, thereby helping millions of children obtain a healthy start. In states that have expanded Medicaid coverage to low-income adults, this coverage not only provides many documented benefits to those adults, but also has added benefits for children and adolescents, including an increased likelihood that they are covered, improved access to needed care, improved financial security for the family, higher preventive care use, and other benefits. ;

The direct benefits of Medicaid coverage for children and adolescents are many. In addition to improved access to care and health outcomes, those with Medicaid coverage miss less school, do better in school, are more likely to graduate and attend college, become healthier adults, earn higher wages, and pay more in taxes. Together with CHIP, Medicaid has been instrumental in driving down the rate of uninsurance among children, which stands at 5.7% nationally and 7.6% in Florida (2019).
Medicaid is not a benefit exclusive to cisgendered individuals. Indeed, Medicaid is of vital importance to transgender individuals, as it is estimated that almost 1/3 of all transgender persons will fall below the poverty line, more than twice the rate of the general population. Both cisgender and transgender individuals enrolled in Medicaid rely on the program to cover their necessary medical care. However, the State of Florida, in promulgating this rule, is discriminating against Medicaid's transgender enrollees by seeking to arbitrarily ban a whole category of treatments which is exclusively utilized by transgender individuals.

Unlike many private health insurance plans, Medicaid guarantees that benefits for children are designed specifically for them. The Early and Periodic Screening, Diagnosis and Treatment (EPSDT) provision of federal Medicaid law is a cornerstone Medicaid protection and the definitive gold standard of pediatric health care benefits. EPSDT guarantees that all Medicaid-eligible children are screened to assess and identify health issues early and ensures the provision of medically necessary health services to address those identified health conditions. EPSDT is designed to attend to a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT ensures that the medically necessary health care needs of the individual child determine what services and treatments Medicaid ultimately covers for that child. Such decisions of medical necessity are based on the expertise of the pediatrician or other treating clinician, who, through years of education, clinical training, and practice, takes into consideration the widely accepted evidence-based standards of care for the condition being treated.

This regulation as proposed would usurp this process of expert clinical decision-making made in the context of the physician-patient relationship; instead, it seeks to codify a discriminatory ban on widely accepted evidence-based standards of care for transgender adolescents and other individuals. As described in detail above, these standards of care are evidence-based and recommended by the medical community. Presented under the guise of an alternative care standard, this proposed prohibition on specific treatments for gender dysphoria not only ignores the prevailing consensus of numerous medical organizations, but also seeks to jettison the role of the treating clinician in determining medically necessary care for an individual. In every way, this proposed ban is a discriminatory gutting of the practice of medicine for transgender adolescents and other individuals, seeking to stifle the physician-patient relationship and replace it with the state's entirely ideological interest in ending gender affirming care in Florida's Medicaid program. In so doing, this proposed rule ignores the health and well-being of children, adolescents, and other individuals in Florida, both now and in the future, who could benefit from these treatments, and places their health interests as secondary to that of the state. This proposed rule counters medical consensus, discriminates against transgender adolescents, obstructs the physician-patient relationship, subverts Medicaid's EPSDT protection that places medical judgment central to coverage determinations, and, if finalized as proposed, would leave transgender adolescents and other individuals enrolled in Florida Medicaid with nowhere to turn for their much-needed health care.

The consequences of such actions are likely to be many. As detailed throughout this letter, the mental and physical health and well-being of transgender children and adolescents often rely on their abilities to access much needed mental and physical health care—care that is in keeping with the widely recognized evidence-based standards of care for gender dysphoria. In proposing this rule, Florida ignores broad consensus among the medical community as to what those evidence-based standards of care are, and instead seeks, for its own discriminatory reasons, to impose alternate standards and an outright ban of specific treatments for transgender adolescents in the state's Medicaid program. As pediatricians who care for the health and well-being of all children in Florida and across the United

States, we call for the Florida Medicaid program to return to the evidence-based standards of care widely accepted among the medical community, and for this discriminatory ban to be rescinded. Only by doing so will the health and well-being of transgender children and adolescents in Florida be preserved.

Sincerely,

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**Please note: A sourced version of this letter containing footnotes is being provided in PDF format via email.