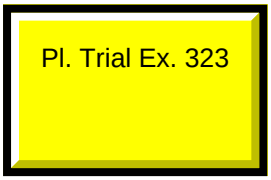
From: FL-Rules@dos.state.fl.us
Sent: Thursday, July 7, 2022 6:05 PM EDT
To: Cole.Giering@ahca.myflorida.com
Subject: One-time User Comment From FLRules.com

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

TABLE OF AUTHORITIES
Authorities & Pages

Christal Achille, et al., Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results, 8 Int'l J. Pediatric Endocrinology 1-5 (2020), https://pubmed.ncbi.nlm.nih.gov/32368216.
Page 3

Luke R. Allen, et al., Well-being and suicidality among transgender youth after gender-affirming hormones, 7(3) Clinical Prac. Pediatric Psych. 302 (2019), https://psycnet.apa.org/record/2019-52280-009.
Page 3

Stewart L. Adelson, Practice parameter on gay, lesbian, or bisexual sexual orientation, gender non-conformity, and gender discordance in children and adolescents, 51 J. Am. Acad. of Child & Adolescent Psychiatry 957, 964 (2020), https://pubmed.ncbi.nlm.nih.gov/ 22917211 ("In contrast, when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood").
Page 3

P Alonso-Coello, HJ Schünemann, J Moberg , et al . GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ 2016;353:i2016.doi:10.1136/bmj.i201
Page 2

J Andrews, G Guyatt, AD Oxman, et al . GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol 2013;66:719–25. doi:10.1016/j.jclinepi.2012.03.013.

Page 2

I Neumann, N Santesso, EA Akl, et al . A guide for health professionals to interpret and use recommendations in guidelines developed with the GRADE approach. J Clin Epidemiol 2016;72:45–55.doi:10.1016/j.jclinepi.2015.11.017
Page 2

Annelou L.C. De Vries, et al., Young adult psychological outcome after puberty suppression and gender reassignment, 134(4) Pediatrics 696-704 (2014).
Page 3

Annelou L.C. de Vries et al., Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study, 8(8) J. Sexual Medicine 2276 (2011), https://pubmed.ncbi.nlm.nih.gov/20646177.
Page 3

R Graham, M Mancher, DM Wolman, S Greenfield, E Steinberg, eds. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011.
Page 1, 2

Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, J. Adolescent Health (2021), https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext.
Page 3

InformedHealth.org [Internet]. Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG); 2006-. What are clinical practice guidelines? 2016 Jun 15 [Updated 2016 Sep 8]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK390308/
Page 1

Rittakerttu Kaltiala, et al., Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria, 74(3) Nordic J. Psychiatry 213 (2020.
Page 3

Laura E. Kuper, et al., Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy, 145(4) Pediatrics e20193006(2020), https://pubmed.ncbi.nlm.nih.gov/32220906.
Page 3

Diego Lopez de Lara, et al., Psychosocial assessment in transgender adolescents, 93(1) Anales de Pediatria 41-48 (English ed. 2020), https://www.researchgate.net/publication/342652073.
Page 3

Simona Martin et al., Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Case 2:22-cv-00184-LCB-SRW Document 91-1 Filed 05/04/22 Page 8 of 32
Page 3

M. Hassan Murad et al., Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes, 72(2) Clinical Endocrinology 214 (Feb. 2010), https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2265.2009.03625.x; see also Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, supra note 50.
Page 4

Stephen M. Rosenthal, Challenges in the care of transgender and gender-diverse youth: an endocrinologist's view, 17(10) Nature Rev. Endocrinology 581, 586 (Oct. 2021), https:// pubmed.ncbi.nlm.nih.gov/34376826.
Page 3

Jack L. Turban, et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, J. Plos One (2022), https://journals.plos.org/plosone/article?id=10.1371/ journal.pone.0261039.
Page 3

Jack L. Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC7073269.
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Cases & Pages
Brandt v. Rutledge, 551 F. Supp. 3d 882, 890 (E.D. Ark. 2021)
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