January 19, 2024

Bruce Vanderhoff
Director
Ohio Department of Health

LeeAnne Cornyn
Director
Ohio Department of Mental Health & Addiction Services

Submitted electronically to ODHrules@odh.ohio.gov and MH-SOT-rules@mha.ohio.gov

RE: Comments on Draft Rules: 3701-3-17; 3701-59-06; 3701-83-61; 5122-26-19; and 5122-14-12

Dear Directors Vanderhoff and Cornyn:

On behalf of the American Civil Liberties Union (ACLU) and the American Civil Liberties Union of Ohio, we are submitting comments on the above-listed rules related to gender-affirming medical care for transgender people in Ohio.

Founded in 1920, the ACLU works in the courts, legislatures, and communities to defend and preserve the individual rights and liberties guaranteed to all people in this country by the Constitution and laws of the United States. The ACLU includes more than 500,000 members in all 50 states, making it our country's foremost advocate of individual rights. As an affiliate of the ACLU, the ACLU of Ohio has 28,000 members and supporters statewide, and in every county. The ACLU of Ohio appears routinely in state and federal courts and the legislature to defend civil rights and advance the civil liberties of all people.

Together, we work to ensure that all LGBTQ people can live openly without discrimination and enjoy equal rights, personal autonomy, and freedom of expression and association. For decades we have represented transgender minors and adults in federal and state courts across the country. Specifically, we have challenged restrictions on the ability of transgender people to access medically-necessary, evidence-based, medical care and know not only the grave harm such restrictions cause the transgender community but also the erosion of fundamental legal protections these types of restrictions represent.

We write with deep concerns regarding the proposed rules. If allowed to go into effect, the regulations could force thousands of transgender Ohioans to go without medical treatment that they and their doctors know they need. The proposed rules represent the single most extreme set

of regulations governing medical treatment for transgender *adults* anywhere in the United States and are wholly out of step with contemporary medical guidelines. We urge the Ohio Department of Health ("ODH") and the Ohio Department of Mental Health & Addiction Services ("ODMHAS") to rescind the proposed rules or, at a minimum, bring them into alignment with current medical guidelines. Our specific analysis follows.

Background Context

In December 2023, the Ohio legislature passed House Bill 68 ("HB 68"). In substance, HB 68 bans gender-affirming medical interventions, including pubertal suppression and cross-sex hormone therapy, only when used to treat transgender minor patients with gender dysphoria. The bill also bans transgender women and girls from participating on girls' sports teams with other women and girls. On December 29, 2023, Governor DeWine vetoed House Bill 68. In his veto message, Governor DeWine explained of his decision:

> I believe this is about protecting human life. Many parents have told me that their child would be dead today if they had not received the treatment they received from an Ohio children's hospital. I have also been told, by those that are now grown adults, that but for this care, they would have taken their lives when they were teenagers.[1]

In his statement, Governor DeWine expressed concern about two potential aspects of treatment in Ohio. The first, was what he claimed was a lack of data on the treatment being provided. The second, was on the hypothetical possibility of care being marketed in medically unsound "pop-up clinics" or "fly-by-night operations" to patients in the state. Governor DeWine then indicated that he would be directing ODH and ODMHAS to promulgate rules to address these concerns. The result of that direction is the above-referenced proposed rules.

Subsequent to the publication of the proposed rules concerning gender-affirming medical treatment for transgender people, the Ohio House of Representatives overrode Governor DeWine's veto of HB 68 on January 10, 2024. The Senate is expected to override the veto on or around January 24, 2024, after which, the provisions of HB 68 will go into effect in the early Spring, and will, among other things, categorically ban gender-affirming medical treatment for transgender minors in Ohio.

The Impact of the Draft Rules

If allowed to go into effect as written - or at all - these rules will amount to the single most sweeping restrictions on medical care for transgender adults anywhere in the United States. Rather than regulating to require data collection and prohibit medically unsound pop-up clinics per the Governor's instruction, the rules impose sweeping constraints on care for all transgender people - minors and adults alike - with no grounding in existing medical science.

[1] https://content.govdelivery.com/attachments/OHIOGOVERNOR/2023/12/29/file_attachments/2731770/Signed%20Veto%20Message%20HB%2068.pdf

In particular, the proposed rules would require all providers of treatment to transgender patients in Ohio to comply with onerous reporting requirements and contract with multiple specialists only when treating transgender patients with gender-affirming medical treatment. There is no basis in science or medicine to single out treatment for transgender patients for these additional burdens. By their plain terms, the rules govern care when that care is "provided for the purpose of assisting an individual with gender transition that seeks to alter or remove physical or anatomical characteristics or features that are *typical* for the individual's biological sex, or to instill or create physiological or anatomical characteristics that resemble a sex *different* from the individual's birth sex." 5701-59-07 (A)(6) (emphasis added). In other words, the care restrictions turn on whether or not the government deems the treatment typical or not with a person's sex designated at birth. A medical provider could, for example, treat any adult patient - assigned male or female at birth - with testosterone for any purpose provided it was not deemed atypical for the patient's birth sex designation. This would include, for example, a cisgender man with low testosterone, a cisgender woman with a reduced sex drive, or even a cisgender man who wanted to increase muscle tone. But if an individual assigned female at birth needed testosterone to treat gender dysphoria, the state would require the clinician to contract with an endocrinologist and a psychiatrist, and consult an ethicist before providing treatment. The singling out of health care only for transgender people has no basis in medicine and could result in a dangerous reduction of care.

Treatment of transgender individuals with gender dysphoria is governed by the World Professional Association for Transgender Health's Standards of Care, now in its eighth edition, and the Endocrine Society's Clinical Practice Guideline.[2] The treatment protocols outlined in these guidelines are recognized and accepted by every major medical association in the United States.[3] Ohio's proposed rules bear no resemblance to existing medical guidelines and though the majority of concerns outlined by the Governor and in the legislative debate over HB 68 focused on care for minors, the proposed rules will almost exclusively constrain care for adults in light of the background legal context.

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[2] Coleman, E., et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health, 23:sup1, S1-S259, DOI: 10.1080/26895269.2022.2100644. Available athttps://doi.org/10.1080/26895269.2022.2100644 (hereafter, "WPATH SOC 8").5 Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L.,et al. Endocrine Treatment of Gender- Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.The Journal of Clinical Endocrinology & Metabolism. 2017; 102(11):3869- 3903 (hereafter, "Endocrine Society Guideline").

[3] *See*, *e.g.*, Rafferty, J., Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence and Section on Lesbian, Gay, Bisexual, & Transgender Health and Wellness. Policy Statement: Ensuring Comprehensive Care and Support for Transgender andGender Diverse Children and Adolescents. Pediatrics. 2018; 142(4):2018-2162. Available at: https://pediatrics.aappublications.org/content/142/4/e20182162; Beers, L.S. American Academy of Pediatrics Speaks Out Against Bills Harming Transgender Youth. American Academy of Pediatrics. 2021. Available at: https://services.aap.org/en/news- room/news-releases/aap/2021/american-academy-of-pediatrics-speaks-out-against-bills- harming-transgender-youth/; AACAP Statement Responding to Efforts to Ban Evidence- Based Care for Transgender and Gender Diverse Youth. American Academy of Child & AdolescentPsychiatry. 2019. Availableat: https://www.aacap.org/AACAP/Latest_News/AACAP_Statement_Responding_to_Effort s-to_ban_Evidence-Based_Care_for_Transgender_and_Gender_Diverse.aspx; State Advocacy Update. American Medical Association. 2021. Available at: https://www.ama-assn.org/health-care-advocacy/advocacy-update/march-26-2021-state-advocacy-update. 8 Endocrine Society Guideline at 3872.Case 3:23-cv-00376 Document 29 Filed 04/21/23 Page 7 of 23 PageID #: 252

By imposing onerous requirements on providers, the proposed rules, if adopted, could severely limit care access for transgender Ohioans, with disastrous consequences to their health and well-being, and even to their survival. To be cut off from treatment is a grave concern for adult patients who have relied on the restricted treatment for years or who, as a result of gonad-removing surgery, literally cannot live without hormone replacement. Likewise, decades of research on care for adolescents and adults has demonstrated that access to hormone therapy and surgery for those who need it greatly improves health outcomes and limiting access to such care can result in increased anxiety, depression and suicidality.[4]

Recommendations

The ACLU and the ACLU of Ohio urge ODH and ODMHAS to fully rescind these proposed rules. With respect to minors, the rules are almost completely superfluous in light of HB 68. They impose restrictions on care for minors but by the time the rules go into effect, that care will be categorically banned in the state. The only remaining impact of the rule on care for minors will be to impose restrictions on mental health diagnoses, which undermines, rather than advances, any interest the state claims in ensuring robust mental health assessments.[5] Beyond that, what is left of the rules are a series of burdensome requirements for adult care, out of step with medical guidance, and likely to cause significant harm to Ohioans. Further, in substance, the proposed rules are rife with errors, internal inconsistencies and onerous requirements that will not serve to improve care, but rather, will compromise it.

If ODH and ODMHAS are instead intent on ignoring the prevailing medical norms and standards and ultimately move forward with these proposed rules, at a minimum, certain provisions must be changed to prevent arbitrary care restrictions, internal contradictions, confusion and significant harm to the health and well-being of transgender patients in Ohio:

First, the rules should eliminate any restriction on care for adults. Though the language of the rules is inconsistent, many substantive restrictions apply to medical treatment for transgender people of all ages. For example, the prohibitions on diagnosis or treatment occurring at a "health care facility" have no age limitation. See 3701-83-61 (B). Further, the reporting requirements and the requirements that providers employ or contract with an endocrinologist and psychiatrist have no age limitations. To the extent the goal of the proposed rules is to impose more stringent standards on care for minors, these go well beyond that and should be corrected to clarify they apply to care

[4] See, e.g., Gomez-Gil, E., Zubiaurre-Elorza, L., Esteva, I., Guillamon, A. et al. (2012). Hormone treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology, 37(5), 662–70. Gooren, L.J. (2011). Care of transsexual persons. New England Journal of Medicine, 364, 1251–57. Gorin-Lazard, A., Baumstark, K., Boyer, L., Maguigneau, A., et al. (2012). Is hormonal therapy associated with better quality of life in transsexuals? A cross-sectional study. Journal of Sexual Medicine, 9(2): 531-534. Lane, M., Graham, C., Sluiter, E., et al. (2018). Trends in gender-affirming surgery in insured patients in the United States. Plastic and Reconstructive Surgery, 6(4). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. International Journal of Pediatric Endocrinology,2020(8), 1-5.

[5] See 3701-59-07 (B)(1) (limiting when and how diagnoses of gender dysphoria can be made separate and apart from any subsequent medical intervention).

for minors only. When asked about the proposed rules' impact on adult care, Governor DeWine stated: "We don't want any barriers…We want adults to be able to make those decisions."[6]

Second, as written, proposed rule 5122-26-19 subsection (G) includes an exemption from the requirements of subsection (B) for those who initiated treatment prior to the rule's effective date. However, the exemption only applies to patients under 21. This limitation - which appears to be a product of the initial intent to only regulate care for minors and young adults - has no grounding in medicine, law or ethics. Adult patients may have been relying on the regulated treatment for years, if not decades. Existing patients of all ages must be included within the exemption in subsection (G). Similarly, proposed rule 5701-59-07 subsection (E) provides an exemption from that proposed rule's requirements for those who initiated treatment prior to the effective date of the rule. As drafted, that exemption only applies to minors. Like subsection (G) of 5122-26-19, Subsection (E) must be expanded to cover existing patients of all ages.

Third, as written, the text of proposed rule 5122-14-12 is unclear as to what is limited in inpatient psychiatric settings for patients under 21. The language of the rule could be interpreted to mean that patients in such settings could not *continue* receiving hormone therapy that they were prescribed prior to entering an inpatient treatment facility. It is essential that ODMHAS clarify the language of the rule to make clear that ongoing treatment can be continued. Cutting patients off of treatment while in an inpatient - or in any - setting could have catastrophic physical and psychological health consequences.

Fourth, as written, proposed rule 5122-26-19 subsection (B) and proposed rule 5701-59-09 subsection (C) require that any provider of hormone therapy to adults contract with or employ both an endocrinologist and a psychiatrist. These requirements have no grounding in science and would be overly burdensome to providers who regularly prescribe hormone therapy to transgender and cisgender patients alike. If medical providers are practicing outside of the guidelines and ultimately causing harm to patients, existing medical licensing oversight can address such concerns. Given existing medical regulations, these oversight requirements serve no purpose other than to unnecessarily hinder the practice of medicine.

But if the agencies believe that additional oversight is required here - despite no documentation of such a need - then the oversight should be based on expertise not medical degree. For example, both the WPATH Standards of Care and the Endocrine Society Guideline outline the qualifications needed for a mental health provider to diagnose and assess patients for gender dysphoria.[7] Rather than simply mandating the presence of a psychiatrist with no guaranteed expertise, it would be more consistent with medical practice to require employing or contracting with a mental health provider who has the requisite knowledge and experience in diagnosing and treating gender-related

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[6] *DeWine Touts Relationship with Legislature Amid Override Push*, Gongwer, Jan. 11, 2024, https://www.gongwer-oh.com/news/index.cfm?article_id=930080201.

[7] See, e.g., Endocrine Society Guideline at 3877 (recommending that mental health providers meet the following enumerated qualifications: "(1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings."

psychiatric conditions. Similarly, medical guidelines do not require an endocrinologist to prescribe hormone treatment for gender dysphoria (or any other condition). Both the Endocrine Society Guideline and the WPATH SOC focus on whether the provider has expertise in hormone treatment. Any oversight requirements in the rule should track these medical standards and reference "qualified mental health providers with experience in assessing and treating gender-related conditions and medical providers qualified to initiate and manage hormone-related therapies."

We again note that, in their entirety, these rules are contrary to existing medical standards and serve to impose unnecessary burdens on medical providers and patients. Rescinding these rules is the clearest way the state can protect the health and well-being of all Ohioans.

Thank you for the opportunity to comment on the Draft Rules. If you have any questions, please do not hesitate to contact us.

Sincerely,

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cc: Governor Mike DeWine, *submitted electronically via Giles Allen, Director of Legislative Affairs*