May 2, 2022

EO 12866 Meeting
Removal of Exclusion of Gender Alterations from the Medical Benefits Package
RIN:2900-AR34

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Thank you for the opportunity to provide comments on OIRA's review of the proposed rule, "Removal of Exclusion of Gender Alterations from the Medical Benefits Package."

As OMB cancelled a previous EO 12866 meeting on a different rule it had scheduled with EPPC,[1] we are glad you are willing to hear EPPC scholars' input on this rule.

The Department of Veterans' Affairs (VA) proposes to remove the current exclusion for "gender alterations" from its medical benefits package. The VA states that the purpose of the proposed change is "so that transgender and gender diverse veterans may receive medically necessary health care, including surgical interventions for gender transition. This proposed change would be consistent with medical industry standards and would ensure that VA provides a full continuum of care to transgender and gender diverse veterans."

As explained below, we object to the characterization that such care is "medically necessary" and that it is "consistent with medical industry standards." We object to the proposed change on the grounds listed below and request that the VA provide explanations addressing the points raised.

1. There is no need for federal regulatory action.

- EO 12866, section 1(b) establishes the principles of regulation, including that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem."
- As such, the burden is on the VA to define the problem that it is seeking to address. As discussed more below, we disagree that irreversible and sterilizing medical and surgical interventions are "medically necessary" or "consistent with medical industry standards."

[1] Rachel Morrison, *Biden and Becerra Kill Democratic Norms in Rush to Fund Big Abortion*, NATIONAL REVIEW (Oct. 8, 2021), https://www.nationalreview.com/bench-memos/biden-and-becerra-kill-democratic-norms-in-rush-to-fund-big-abortion/.

As such, there is no need for federal regulatory action to remove the exclusion of gender alternations from the medical benefits package.

2. **The VA must specify the diagnosis requiring treatment and the medical services that will be covered.**
    - The current "gender alterations" exclusion denies coverage for an entire category of medical services. The proposed change seeks to remove that exclusion, but fails to specify the medical services the VA intends to cover as well as any applicable limitations.
    - The proposed change suggests that the VA will authorize coverage of an entire category of medical services, regardless of the disparate levels of evidence associated with each type of intervention. In addition, the proposed change appears to condition eligibility for those services on the patient's membership in a self-defined identity category ("transgender and gender diverse veterans") and the patient's motivation for seeking medical services ("for gender transition"). Extending coverage on those bases is unprecedented and unjustifiable.
        - Consider two patients: Patient A self-defines as "cisgender" and - motivated by a desire for personal and social transformation - seeks breast augmentation surgery. Patient B self-defines as "transgender" and - motivated by a desire for gender transformation - seeks breast augmentation surgery. Would the proposed change authorize equal coverage for the breast augmentation surgeries of Patient A and Patient B? Or would Patient A's breast augmentation be excluded as "cosmetic" and not "medically necessary" because she self-identifies as "cisgender" instead of "transgender"? Or because she seeks breast augmentation to effect a personal transformation rather than a gender transformation?
        - In fact, neither a patient's self-defined identity category (e.g., "transgender") nor a patient's expressed motivation ("for gender transition") qualifies as a medical diagnosis or medical condition for which medical services are "medically necessary."[2]
        - Current regulations require covered medical services, as a condition for inclusion in the medical benefits package, to promote, preserve, or restore health.[3] Closely linked to that purpose is the provider's determination that the desired medical services are "medically necessary" for that purpose—but determining whether or not desired services are "medically necessary" depends, in turn, on the patient's

[2] The National Center for Transgender Equality (NCTE) states that "[o]n its own, being transgender is not considered a medical condition." "Frequently Asked Questions About Transgender People," National Center for Transgender Equality. https://transequality.org/issues/resources/frequently-asked-questions-about-transgender-people Similarly, according to the World Professional Association for Transgender Health (WPATH SOC 7), identifying as "transgender" or "gender diverse" is a natural variant of human experience, *not* a medical or psychological disorder requiring medical interventions. "[T]ranssexual, transgender, and gender-nonconforming individuals are not inherently disordered. Rather, the distress of gender dysphoria, when present, is the concern that might be diagnosable and for which various treatment options are available." WPATH SOC 7, p. 6 (2012).
[3] Title 38, Part 17:32. "Medical Benefits Package." https://ecfr.io/Title-38/Section-17.38 p. 729, provides specific criteria for the inclusion of medical services in the "medical benefits package."

diagnosis, medical condition, expected health-related benefit, and recognized standards of care. For example, Healthcare.gov defines "medically necessary" as "[h]ealth care services or supplies needed to diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine."[4] It is impossible to determine which services are "medically necessary" without first identifying the diagnosis/condition that warrants treatment and then identifying appropriate treatment alternatives.

- In October 2021, HHS's Centers for Medicare & Medicaid Services (CMS) approved Colorado's essential health benefits benchmark plan for individual markets and small groups (fewer than 51 employees) to require insurance coverage for "gender affirming" services that would include, "at minimum": puberty blockers for children (with no stated age minimum); cross-sex hormones; genital and non-genital surgical procedures (hysterectomy, penectomy, mastectomy); blepharoplasty (eye and lid modification); face/forehead and/or neck tightening; facial bone remodeling for facial feminization; genioplasty (chin width reduction); rhytidectomy (cheek, chin, and neck); cheek, chin, and nose implants; lip lift/augmentation; mandibular angle augmentation/creation/reduction (jaw); orbital recontouring; rhinoplasty (nose reshaping); laser or electrolysis hair removal; and breast/chest augmentation, reduction, construction.[5]
- Although we disagree—for many of the same reasons expressed in this document—with the HHS/CMS decision to approve Colorado's essential health benefits benchmark plan, the HHS/CMS decision to list the specific medical services approved for coverage is appropriate. We request a similar listing of covered services if the VA proceeds with the planned removal of the "gender alterations" exclusion.
- If the VA wants to provide coverage for medical services linked to the DSM-V diagnosis of "gender dysphoria," then it should clearly specify "gender dysphoria" as the diagnosis/condition that warrants coverage and identify the medical and surgical interventions that will be covered as "medically necessary" treatments.[6]

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[4] "Medically Necessary," *Glossary*, Healthcare.gov. https://www.healthcare.gov/glossary/medically-necessary/. Similarly, Medicare.gov closely links the definition of "medically necessary," under Medicare Part B, to the patient's diagnosis or medical condition, defining "medically necessary" as "[s]ervices or supplies that are needed to diagnose or treat your medical condition and that meet accepted standards of medical practice." "What Part B Covers," Medicare.gov. https://www.medicare.gov/what-medicare-covers/what-part-b-covers.

[5] Press Release, Ctrs. For Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado (Oct. 12, 2021), https://www.cms.gov/newsroom/press-releases/biden-harris-admin-istration-greenlights-coverage-lgbtq-care-essential-health-benefit-colorado; DIV. OF INSURANCE, COLO. DEP'T OF REGULATORY AGENCIES, BENEFITS FOR HEALTH CARE COVERAGE: COLORADO BENCHMARK PLAN 38 (May 7, 2021), *available at* https://doi.col-orado.gov/insurance-products/health-insurance/aca-information/aca-benchmark-health-insurance-plan-selection (click on "Benchmark plan changes – submission documents" and open document titled "Colorado Benchmark plan for 2023.pdf").

[6] The DSM-V lists specific criteria for a diagnosis of "gender dysphoria" in adolescents/adults, including the presence of "clinically significant distress or impairment." Garg G, Elshimy G, Marwaha R. Gender Dysphoria. [Updated 2022 Feb 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK532313/.

3. **"Gender affirming" medical and surgical interventions are not "medically necessary" treatments for "gender dysphoria."**

- Gender dysphoria can be addressed in ways that do not require medical or surgical interventions. According to the Human Rights Campaign, even "gender transition" is not synonymous with seeking medical or surgical interventions: "Transitioning does not always involve medical treatment. By dressing in preferred clothing, changing your body through diet or exercise, adjusting mannerisms and speech patterns, and requesting that friends, family and others address you with different names and pronouns, you can live closely aligned to your true gender" (*Coming Out: Living Authentically as Transgender or Non-binary*, p. 34).[7]
- The scientific evidence to date contradicts the claim that "gender-affirming" medical and surgical interventions are ever "medically necessary."[8] An extensive, new review article highlights "[f]ive scientific observations [that] question and refute the assumption that an individual's experience of incongruence of sex and gender identity is best addressed by supporting the newly assumed gender identity with psychosocial and medical interventions."[9] In sum, these factors weigh against medical and surgical interventions:
    - "The most foundational aspect of the diagnoses of "gender dysphoria" (DSM-5) and "gender incongruence" (ICD-11), requisite for the provision of medical treatment, is in flux, as professional disagree on whether the presence of distress is a key diagnostic criterion…
    - [N]o randomized controlled studies demonstrate[e] the superiority of various affirmative interventions compared to alternatives. There isn't even agreement about which outcome measures would be ideal in such studies…
    - There are few long-term follow-up studies of various interventions using predetermined outcome measures at designated intervals. Studies that have been conducted are, at best, inconsistent. Higher quality studies with longer-follow-up fail to demonstrate durable positive impacts on mental health…

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[7] *Coming Out: Living Authentically as Transgender or Non-binary*, Human Rights Campaign Foundation, 34. (2020). https://www.hrc.org/resources/coming-out-living-authentically-as-transgender-or-non-binary.

[8] Leading gender clinicians acknowledge the lack of agreement among specialists as to what constitutes "medically necessary" care in the field of "transgender medicine." Some clinicians, such as Dr. Joshua Safer of Mount Sinai, advocate for inclusion of a broad range of "gender-affirming" medical and surgical interventions by seeking to redefine "medically necessary" beyond its current meaning. According to Dr. Safer, "Differential coverage of gender-affirming surgical procedures by healthcare payers …should be prioritized as medically necessary if [those gender-affirming procedures] are critical to personal safety and to alignment between body and gender identity." Kumar A, Amakiri UO, Safer JD. Medicine as constraint: Assessing the barriers to gender-affirming care. Cell Rep Med. 2022 Feb 15;3(2):100517. doi: 10.1016/j.xcrm.2022.100517. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8861822/ Redefining the definition of "medically necessary" to include social goals such as "personal safety" or identity "alignment" appears similar to the proposed regulatory changes at issue here, which extend coverage based on social identity and personal motivation. But this novel redefinition is not permitted under current regulations and is inconsistent with prevailing medical practice.

[9] Stephen B. Levine, E. Abbruzzese & Julia M. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221. https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221.

- Rates of post-transition desistance, increased mental suffering, increased incidence of physical illness, educational failure, vocational inconstancy, and social isolation have not been established…
- Numerous cross-sectional and prospective studies of transgender adults consistently demonstrate a high prevalence of serious mental health and social problems as well as suicide…"[10]

- When "gender dysphoria" is treated with "gender-affirming" medical and surgical interventions (such as puberty blockers, anti-androgens, cross-sex hormones, and surgical procedures that alter, augment, or remove healthy breast tissue, remove healthy reproductive organs such as testes, ovaries, or uterus, or alter or remove healthy genitalia), the weight of evidence shows no long-term benefits, significant complications, continued mental health issues, and reduced lifespans. Although defenders of gender-affirming medical and surgical interventions claim that these interventions reduce the risk of suicide in transgender-identified persons, the evidence contradicts those claims.
  - In 2020, a longitudinal study by Dutch researchers found that suicides occurred at all stages of "gender transition," and the average time to suicide was six years after medical transition began.[11]
  - A 2011 study of transgender-identified adults who had undergone genital surgery showed long-term declines in mental health, and suicide rates 19 times higher than the general population.[12]
  - A 2020 longitudinal study compared transgender-identified adults who underwent genital "gender-affirming" surgeries with those who did not undergo surgery and found no benefit to surgery, as measured by utilization of mental health services and hospitalizations after suicide attempts.[13]
  - Several recent literature reviews and meta-analyses of studies related to "gender-affirming" surgeries, such as those colloquially described as "top surgery," "bottom surgery," and "facial feminization surgery," describe the research in these areas as suffering from serious limitations, including: sampling bias, use of various unvalidated instruments to measure outcomes, high numbers of patients lost to follow-up (precluding accurate assessments of outcomes), an over-focus on

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[10] Stephen B. Levine, E. Abbruzzese & Julia M. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221

[11] Wiepjes, C. M., den Heijer, M., Bremmer, M. A., Nota, N. M., Blok, C. J. M., Coumou, B. J. G., & Steensma, T. D. (2020). Trends in suicide death risk in transgender people: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972–2017)). *Acta Psychiatrica Scandinavica*, *141*(6), 486–491. doi:10.1111/acps.13164

[12] Dhejne, C., Lichtenstein, P., Boman, M., Johansson, A. L. V., Långström, N., & Landén, M. (2011). Long-term follow-up of transsexual persons undergoing sex reassignment surgery: Cohort study in Sweden. *PLoS ONE*, *6*(2), e16885. doi:10.1371/journal.pone. 0016885.

[13] Bränström, R., & Pachankis, J. E. (2020). Correction to Bränström and Pachankis. (2020). *American Journal of Psychiatry*, *177*(8), 734–734. doi:10.1176/appi.ajp.2020.1778correction. https://ajp.psychiatryonline.org/doi/epub/10.1176/appi.ajp.2020.1778correction. Original Article: Bränström, R., & Pachankis, J. E. (2020). Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: A total population study. *American Journal of Psychiatry*, *177*(8), 727–734. doi:10.1176/appi.ajp.2019.19010080.

reporting effectiveness of techniques and inadequate assessment of the risks and benefits to patients, short-term follow-up, gaps in research, and a concentration of studies reporting outcomes from single, high-volume centers or clinical practices.[14]

- The Centers for Medicare and Medicaid Services (CMS) has refused to issue a National Coverage Determination for "gender reassignment surgery," citing the lack of evidence that such surgeries are medically necessary or beneficial to the Medicare population.
    - In 2016, CMS conducted a National Coverage Analysis reviewing the evidence relating to "gender reassignment surgery" and its suitability as a treatment for gender dysphoria. The CMS Decision Memo, which includes the summary of evidence reviewed, is linked below: The CMS declined to issue a National Coverage Determination.[15] Coverage decisions continue to be made on a case-by-case basis. In its Decision Memo, the CMS noted that the studies reported "conflicting" results, "inconclusive" and poor quality evidence regarding the relative risks and benefits of "gender reassignment surgery" for the Medicare population.[16]
    - CMS noted that "[a]ll studies reviewed had potential methodological flaws" and concluded that: "Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up."[17]
    - In sum, "gender-affirming" medical and surgical interventions are unsupported by evidence and fail to qualify as "medically necessary" treatments for "gender dysphoria." They should continue to be excluded from coverage unless the VA intends to acknowledge these interventions as "experimental" (and thus subject to additional safeguards for experimental medical services) and seeks to expand coverage on that basis.

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[14] Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice). Ann Surg. 2022 Jan 1;275(1):e52-e66. doi: 10.1097/SLA.0000000000004728. PMID: 33443903; Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 2: Genital Reconstruction). Ann Surg. 2022 Jan 1;275(1):e67-e74. doi: 10.1097/SLA.0000000000004717. PMID: 34914663.

[15] Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=368&ncdver=1.

[16] "Gender Dysphoria and Gender Reassignment Surgery," National Coverage Analysis: Decision Memo, CAG-00446N, August 30, 2016. Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282. For history, see https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=368&ncdver=1.

[17] "Gender Dysphoria and Gender Reassignment Surgery," National Coverage Analysis: Decision Memo, CAG-00446N, August 30, 2016. Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282. For history, see https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=368&ncdver=1.

4. **"Gender-affirming care," including medical and surgical interventions promoted as first-line treatments for "gender dysphoria," is not governed by internationally accepted, evidence-based "standards of care."[18]**

- The Endocrine Society's Clinical Practice Guidelines do not endorse the use of "gender-affirming" medical and surgical interventions for purposes of gender transition. However, the guidelines include a "disclaimer" that specifically states that "The Endocrine Society's clinical practice guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care.* The guidelines are not intended to dictate the treatment of a particular patient" (emphasis added)."[19] In addition, the Endocrine Society guidelines are based primarily on evidence that is graded "low" or "very low" in quality, yielding, for the most part, "weak" recommendations.[20]
- Although some insurers cite the WPATH "Standards of Care" (SOC) for determining whether medical services are "medically necessary," WPATH SOC 7 (and SOC 8, in draft) fail to meet the accepted criteria for "standards of care." They are self-described "flexible clinical guidelines," which clinicians freely modify or disregard entirely.[21]
- Even "gender-affirming" medical specialists do not regard WPATH SOC 7 as an appropriate standard of care. For example, a 2022 meta-analysis of "gender-affirming surgeries" (GAS) exposes the ineffectiveness of WPATH's guidelines as a framework for consistent, high-quality research and clinical practice, noting that "[a]lthough the World Professional Association for Transgender Health policies set guideline recommendation for clinical decision-making, the evidence base remains widely scattered, with no reviews that unify gender surgery across all facets."[22]

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[18] For a detailed discussion of what constitutes "evidence-based" medicine, see: Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ (Clinical research ed.)*, *312*(7023), 71–72. https://doi.org/10.1136/bmj.312.7023.71; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2349778/.

[19] Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658. Erratum in: J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. Erratum in: J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759. PMID: 28945902. https://pubmed.ncbi.nlm.nih.gov/28945902/.

[20] Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658. Erratum in: J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. Erratum in: J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759. PMID: 28945902. https://pubmed.ncbi.nlm.nih.gov/28945902/.

[21] "Standards of Care for the Health of Transsexual, Transgender, and Gender- Nonconforming People," World Professional Association for Transgender Health (2012).

[22] Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice). Ann Surg. 2022 Jan 1;275(1):e52-e66. doi: 10.1097/SLA.0000000000004728. PMID: 33443903.

- In 2020, a leading center for "gender-affirming" treatment, the Mount Sinai Center for Transgender Medicine and Surgery, published a study showing that WPATH SOC 7 "guidelines" are widely disregarded, "impractical," and viewed as a "barrier to care." Mt. Sinai developed their own protocols for transgender surgery—protocols that diverge widely from WPATH guidelines.[23]

5. **The lack of standards and poor evidence base for "gender-affirming" interventions likely preclude the possibility of meaningful informed consent.**

- Given that the evidence fails to show long-term benefits of "gender-affirming" medical or surgical interventions, while showing persistently high rates of suicide, mental health issues, reduced lifespan among recipients of "gender-affirming" interventions, serious gaps in evidence-based research, and lack of accepted standards of care, it is questionable whether patients can give meaningful "informed consent" to these medical services, as required by the regulations.
- "Informed consent" under the applicable regulation requires the medical provider to "*explain* in language understandable to the patient… *the nature of a proposed procedure or treatment*; the expected *benefits*; reasonably foreseeable associated *risks, complications or side effects*; reasonable and available *alternatives*; and anticipated *results if nothing is done*."[24]
    - As previously discussed, the evidence base relating to "gender-affirming" medical and surgical interventions is low quality, fails to show long-term benefits to patients, and suffers from significant gaps relating to long-term outcomes, risks, and complications. But "gender-affirming" also interventions raise serious ethical concerns because of their impact on reproduction and fertility. The vast majority of transgender-identified persons have healthy, fully-functioning bodies—before they begin "gender-affirming" interventions. The use of cross-sex hormone treatments degrades fertility for a time, possibly irreversibly; "gender-affirming" surgeries that remove reproductive organs or genitals cause immediate irreversible sterility. These life-changing consequences receive too little attention. A 2020 evidence review, titled "Impact of Exogenous Testosterone [T] on Reproduction in Transgender Men," warns of a "paucity of literature" on the links between cross-sex hormone use and future fertility (or sterility) in transgender-identified persons. The review describes "the effects of long-term T therapy on reproductive function in transgender men, as well as the reversibility of any T-induced changes" as "largely unknown." Consequently, the "current knowledge

[23] Lichtenstein, M., Stein, L., Connolly, E., Goldstein, Z. G., Martinson, T., Tiersten, L., Shin, S. J., Pang, J. H., & Safer, J. D. (2020). The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care Than WPATH SOC 7 Criteria Before Transgender-Specific Surgery. *Transgender health*, *5*(3), 166–172. https://doi.org/10.1089/trgh.2019.0066.
[24] Title 38, Part 17:32. "Informed Consent." https://ecfr.io/Title-38/Section-17.32.

gaps preclude evidence-based counseling for transgender men about fertility treatment options."[25]

- It is deeply troubling that "transgender medicine" provides few if any consistent safeguards to ensure that every patient receives complete information about the infertility risks of gender-affirming interventions, the irreversible nature of "transition-induced" sterility, and alternative treatments for gender dysphoria—*before* the patient gives consent to sterilizing "gender-affirming" interventions.
- In contrast, the federal government uses a detailed informed consent process for sterilizations covered under federal family planning projects, with detailed information forms, required signatures from provider and patient, and audited record-keeping.[26]
- In our view, the lifelong human costs of sterilizations that result from "gender-affirming" medical and surgical interventions cannot be justified. In addition, the gender industry's complicity in promoting the sterilization of otherwise healthy young adults is a serious violation of human rights. On that basis alone, "gender-affirming" (sterility-inducing) medical treatments and surgeries should be excluded from coverage.
- Regrettably, trends within the novel field of "transgender medicine" suggest a move towards *less* consideration of non-medical/surgical alternatives, and disproportionate deference to patient goals and desires at the expense of providing an evidence-based assessment of the likely clinical outcomes and data on long-term risks and benefits. Although styled as an "informed consent" model, these practice trends fail to ensure meaningful informed consent. They capitulate to activists' calls for less "medical gatekeeping" and facilitate "on demand" body modifications as an expression of self-defined identity. The human costs, however, are significant.

6. CMS recently declined to extend insurance coverage to gender transition treatments.

- In January 2022, CMS issued a proposed rule that would have required all insurers of individual market and small group plans across the country to cover the same gender transition services covered under Colorado's plan.[27] The proposal would also have amended benefit design requirements in fully-insured large group plans (more than 50 employees) so that excluding coverage of treatments for gender dysphoria could be considered "presumptively discriminatory."[28] These new requirements would have resulted from the proposal to add "sexual orientation and gender identity" nondiscrimination provisions to several federal insurance regulations.[29] To the surprise of many, when CMS finalized the rule at the end of April 2022, it did so without the

[25] Moravek, M. B., Kinnear, H. M., George, J., Batchelor, J., Shikanov, A., Padmanabhan, V., & Randolph, J. F. (2020). Impact of Exogenous Testosterone on Reproduction in Transgender Men. *Endocrinology*, *161*(3), bqaa014. https://doi.org/10.1210/endocr/bqaa014; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7046016/.
[26] https://omb.report/icr/201810-0937-003.
[27] 87 Fed. Reg. 584, 597.
[28] *Id.* at 595–97, 667.
[29] *Id.* at 595–97.

proposed sexual orientation and gender identity nondiscrimination provisions.[30] The VA should follow CMS's lead and decline to extend insurance coverage to gender transition services at this time.

7. The Rule must sufficiently explain why it is not economically significant.

- The rule summary states that the rule is not major or economically significant. To make that determination, the agency, at a minimum, must establish:
  - Which services, procedures, treatments, drugs, surgeries, etc. will be required to be covered by insurance.
  - Whether coverage includes services for those who wish to "detransition" according to their gender identity "realigning" with their biological sex.
  - The number of gender transition or "detransition" surgeries and treatments expected to be covered by insurance.
  - The cost of each gender transition or "detransition" service to be covered.
  - The insurance costs associated with any follow-up or complications of the newly covered services.
  - The number of veterans expected to undergo each newly covered service.
  - The cost to taxpayers to cover such services.
- Without this analysis, the determination that the rule is not economically significant will be arbitrary and capricious.

8. The Rule should have a meaningful public comment period of at least 60 days.

- As you know, under EO 12866, for most rules, an agency should give the public at least 60 days for meaningful comment. The Administrative Procedure Act (APA) suggests less than 30-days is highly suspect and problematic. Any shorter would further suggest that the VA has prejudged the rule and is not interested in the public's input. Surely fairness and equity require that the public should have a reasonable amount of time of at least 60 days to consider and comment on the proposal.
- We also ask that this date be from publication at the Federal Register, not public inspection. There has been a concerning trend by this administration of providing the public less than 30 days for comment from publication of the notification of proposed rulemaking in the federal register. (For example, CMS published a 145-page, triple-columned notice of proposed rulemaking on January 5 with a public comment deadline on January 27—a mere 22 days to provide input on a complex, major, and economically significant proposed rule. That comment period was outrageously short and should not be repeated.)

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[30] Fact Sheet, Ctrs. For Medicare & Medicaid Servs., HHS Notice of Benefit and Payment Parameters for 2023 Final Rule Fact Sheet (Apr. 28, 2022), https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2023-final-rule-fact-sheet.

Conclusion

We urge OIRA to ensure that the statutory and regulatory process is upheld, and that the proposed rule has sufficient legal and economic analysis that is rationale and reasoned, not political, rushed, or prejudged.