



**Thomas More
SOCIETY**



**CHRISTIAN
LEGAL SOCIETY**



**THE NATIONAL CATHOLIC
BIOETHICS CENTER**

NAE | National Association of
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Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Subj: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2023, File Code CMS-9911-P, RIN 0938-AU65

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops, Christian Legal Society, National Association of Evangelicals, National Association of Catholic Nurses, U.S.A., The National Catholic Bioethics Center, and Thomas More Society, we respectfully submit the following comments on the proposed rule, published in 87 Fed. Reg. 584 (Jan. 5, 2022), in the above-captioned matter.

We applaud HHS's effort to ensure that everyone has access to health care and health coverage, but we object to language in the proposed regulations that can be read to require the provision and coverage of procedures that are medically ineffective or cause harm, violate professional and evidence-based judgments as to an appropriate course of treatment, or conflict with the religious and moral convictions of health insurers, plan sponsors, and other stakeholders.

I. Access to Health Care

Ensuring access to health coverage and health care, and removing barriers to these, is without question a laudable goal. The Universal Declaration of Human Rights states that

“Everyone has a right to a standard of living adequate for the health and well-being of himself and of his family including ... medical care,” thus acknowledging health care as a basic human right. Catholic teaching agrees. “Concern for the health of its citizens requires that society help in the attainment of living conditions that allow them to grow and reach maturity ... [which includes] health care...” Catholic Catechism, no. 2288. Health care should be available to everyone and, toward that end, no one should be without health coverage nor discriminated against in that regard.

II. Mandated Coverage

Unfortunately, the proposed regulations go beyond access to care by suggesting that nondiscriminatory health plans must cover procedures that are not medically indicated, may harm rather than heal, and may violate the religious and moral convictions of an insurer, plan sponsor, or other stakeholder. Most problematic are the provisions of the proposed regulations that relate to “gender identity” and that, read in conjunction with the preamble, appear to mandate coverage of “gender transition” procedures.

Protecting patients from discrimination on the basis of gender identity, as the proposed regulations in part aim to do, need not, and ought not, include a mandate to cover gender transition procedures. Nondiscrimination should guarantee persons, regardless of the gender with which they self-identify, the same medical care as anyone else across all indications, such as treatment for the flu or a broken leg, without harassment or difference in care. Declining to cover a particular procedure because it is harmful or ineffective, or because the procedure itself is morally objectionable regardless of the identity of the patient in question, is, on the other hand, not discrimination at odds with the goals of the Department in ensuring access to care for everyone.

A. Relevant Principles

A mandate to cover gender transition procedures is in tension with two principles that animate health care and health insurance.

First, the health care profession, precisely because it is a profession, requires the exercise of judgment on the part of a patient’s physician or other health care provider, which is necessarily related to an insurer’s or plan administrator’s evidence-based judgment as to what is appropriately covered. Patients, to be sure, have a right to be involved in their own health care, but they do not have a right to a treatment that professional medical judgment concludes will (a) fail to cure the patient, (b) fail to alleviate his or her condition, or (c) do affirmative harm. The health care profession is not a vending machine. A patient does not simply put in a token and obtain any item or procedure of his or her choosing.

Second, many insurers and plan sponsors, especially those with a religious affiliation, provide health coverage based on, and indeed because of, their underlying religious and moral views about the dignity and sanctity of human life. The provision of health coverage by religious employers and religious insurers is part and parcel of their religiously-motivated goal to

provide coverage for medical procedures that will heal or otherwise benefit their employees or insureds. No insurer or plan sponsor should be required, as a condition of providing such benefits, to violate the very religious and moral convictions that prompt them to offer those benefits in the first place.

B. Application to the Proposed Rule

In tension with these two principles, the proposed section 147.104 states:

A health insurance issuer ... cannot employ ...benefit designs that will ... discriminate based on an individual's ... sexual orientation [or] gender identity.

As a preliminary matter, the scope of this particular proposed revision warrants clarification. HHS should make clear whether it will interpret this provision to apply to the benefit designs of any plans offered outside the federally-facilitated and State-based Exchanges, and if so, under what circumstances. For instance, would this provision govern fully insured group health plans sponsored by employers? Would entities that operate as both health insurance issuers and third-party administrators of self-insured plans be subject to this provision? The answers to these questions will have significant consequences for the scope of the proposed rule's impact on religious freedom. However, even if the regulation is limited to the federally-facilitated and State-based Exchanges, the proposed rule will present religious freedom concerns for religious entities operating in those markets.

In addition to the proposed section 147.104, there are several other instances in which the proposed regulations (e.g., sections 155.120, 155.206, 156.200, and 156.1230) forbid "discrimination" on the basis of sexual orientation or gender identity. Though the proposal does not define "discriminate" or "discrimination," the preamble states that HHS regards the decision not to cover gender transition procedures as presumptively discriminatory. *See, e.g.*, 87 Fed. Reg. at 667 ("[E]xcluding coverage of medically necessary hormone therapy for treatment of gender dysphoria where hormone therapy is otherwise a covered EHB [i.e., essential health benefit] is presumptively discriminatory.").

A presumption of discrimination based on a decision not to cover gender transition procedures tilts the scales inappropriately in favor of a finding of discrimination even where there is none. Like many health care providers, we believe that medical and surgical interventions that purport to alter one's sex are, in fact, detrimental to patients. Such interventions are not properly viewed as health care because they neither cure nor prevent disease or illness. Surgical alteration of the genitalia, in particular, mutilates the body by taking a healthy bodily system and rendering it dysfunctional.¹ We expect that many insurers, plan sponsors, and individual purchasers will find mandatory coverage of such procedures

¹ See Richard P. Fitzgibbons, M.D., et al., *The Psychopathology of "Sex Reassignment" Surgery: Assessing its Medical, Psychological and Ethical Appropriateness*, National Catholic Bioethics Quarterly 97, 100 (Spring 2009).

objectionable—not because of any discriminatory animus, but because they understand them to be bad medicine.

Changes in attitudes and conceptualizations of gender, gender dysphoria, and gender-related procedures, no matter who embraces them, do not eliminate the serious questions that medical research has raised concerning the health outcomes of such procedures. In 2020, for example, a study employing the world’s largest data set on patients receiving “gender-affirming” surgeries was corrected, saying that “the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care.” The same study had already similarly found no benefit from hormonal procedures. Richard Branstrom & John E. Pachankis, *Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study*, AM. J. PSYCHIATRY, 177:734 (Aug. 2020) (republished for correction).

A study by the Karolinska Institute in Sweden, tracking patients over a 30-year period, “revealed that beginning about 10 years after having the surgery, the transgendered began to experience increasing mental difficulties. Most shockingly, their suicide mortality rose almost 20-fold above the comparable nontransgender population.” Paul R. McHugh, M.D., *Transgender Surgery Isn’t the Solution: A Drastic Physical Change Doesn’t Address Underlying Psycho-Social Troubles*, WALL STREET JOURNAL (June 12, 2014); see Cecilia Dhejne, et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden* (Feb. 22, 2011) (“Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population”); see also David Batty, *Sex Changes Are Not Effective, Say Researchers*, THE GUARDIAN (July 30, 2004) (“There is no conclusive evidence that sex change operations improve the lives of transsexuals, with many people remaining severely distressed and even suicidal after the operation,” according to a review of more than 100 international medical studies of post-operative transsexual individuals).

HHS itself has had reservations about the efficacy and outcomes of “gender reassignment surgery.” During the Obama administration, the Department declined to issue a national coverage mandate for such surgery in its own programs. Center for Medicare & Medicaid Services, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG-00446N (Aug. 30, 2016) (finding that “the clinical evidence is inconclusive,” that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes,” and that “we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality”).

Hormonal treatment also poses risks. Puberty-delaying hormones administered to children to facilitate later sex-change surgery, for example, “stunt [their] growth and risk causing sterility.” McHugh, *Transgender Surgery Isn’t the Solution*, *supra*. By contrast, decisions not to provide hormonal or surgical interventions have yielded positive results. Vanderbilt University and London’s Portman Clinic report, for example, that a large

percentage of children (70 to 80%) who reported transgender feelings but received no medical or surgical intervention ultimately lost those feelings. *Id.*; see also Thomas D. Steensma, et al., *Desisting and Persisting Gender Dysphoria after Childhood: A Qualitative Follow-up Study*, CLINICAL CHILD PSYCHOLOGY AND PSYCHIATRY, 16:4, 499-516 (Oct. 2011); Kelley D. Drummond, Susan J. Bradley, Michele Peterson-Badali, and Kenneth J. Zucker, *A Follow-up Study of Girls with Gender Identity Disorder*, DEV. PSYCHOLOGY, 44:1, 34-35 (2008); Madeleine S.C. Wallien and Peggy T. Cohen-Kettenis, *Psychosexual Outcome of Gender-dysphoric Children*, J. AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY, 47:12, 1413-23 (2008).²

These outcomes suggest that patients may not be well served, and indeed that their health may actually be harmed, by attempts to “change” their sex. Studies that reach contrary conclusions, on the other hand, are often critically limited either to the short-term or by not adequately considering the high number of persons who are lost to follow-up and do not respond in the long-term. See generally Lawrence S. Mayer and Paul R. McHugh, *Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences*, THE NEW ATLANTIS, no. 50 (Fall 2016). Since the goal of health coverage is at all times to preserve and promote good health, attempts to change sex should not be made a mandatory item of coverage.³ Indeed, given the research and experience, such attempts could expose health care providers to claims of medical malpractice. It is obviously poor regulatory policy to require a plan to cover a procedure in any circumstance where the provision of that procedure would subject a health professional to a malpractice claim.

C. Special Considerations with Respect to Religious Freedom

Finally, a presumption of discriminatory treatment in the refusal to cover gender transition procedures will create conflicts with the federal Religious Freedom Restoration Act (RFRA). HHS is currently a party to litigation in which federal courts have concluded that Department regulations issued under the Affordable Care Act (ACA) violated RFRA by requiring religious stakeholders to provide and cover such procedures. *Franciscan Alliance*

² Cross-sex hormones present their own physical health risks by, in addition to potential sterility, possibly heightening the chances of cardiac disease, high blood pressure, blood clots and stroke, diabetes, gallbladder disease, breast cancer in men, and sleep apnea in women. See T. Alzahrani, *Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population*, CIRCULATION: CARDIOVASCULAR QUALITY AND OUTCOMES, 12:e005597 (2019); N.M. Nota, et al., *Occurrence of Acute Cardiovascular Events in Transgender Individuals Receiving Hormone Therapy: Results From a Large Cohort Study*, CIRCULATION, 139, 1461-62 (2019); D. Getahun, et al., *Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study*, ANN. INTERN. MED., 169:4 (2018); M.S. Irwig, *Cardiovascular Health in Transgender People*, REV. ENDOCR. METAB. DISORD., 19:3 (2018); S. Maraka, et al., *Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis*, J CLIN. ENDOCRINOL. METAB., 102:11 (2017); J. Feldman, G.R. Brown, M.B. Deutsch, et al., *Priorities for Transgender Medical and Healthcare Research*, CURR. OPIN. ENDOCRINOL. DIABETES OBES., 23, 18-87 (2016); D. Macut, I. B. Antić, and J. Bjekić-Macut, *Cardiovascular Risk Factors and Events in Women with Androgen Excess*, J. OF ENDOCRINOLOGICAL INVESTIGATION, 38:3 (2015); E. Moore, A. Wisniewski, A. Dobs, *Endocrine Treatment of Transsexual People: A Review of Treatment Regimens, Outcomes, and Adverse Effects*, J. CLIN. ENDOCRINOL. METAB., 88, 3467-73 (2003).

³ Problems similar to those that we have identified with respect to gender identity may also arise with respect to the inclusion of sexual orientation as a protected category. For example, a person who is a counselee of a health care provider may seek affirmation of a relationship or conduct that conflicts with the provider’s religious or moral convictions. *E.g.*, *Ward v. Polite*, 667 F.3d 727 (6th Cir. 2012) (graduate student expelled from counseling program because of opposition to homosexual conduct stated triable free speech and free exercise claims).

v. Becerra, No. 7:16-cv-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 16, 2021); *Religious Sisters of Mercy v. Azar*, 513 F.Supp.3d 1113 (D. N.D. Jan. 19, 2021). While those court decisions involve section 1557 of the ACA, the proposed regulations, if adopted, would fuel similar litigation in a guise only slightly different from the cases HHS has already lost in court. As a result, the proposal, if adopted in its present form, will draw the government and private parties into yet more litigation, and we expect that the government once again will lose those cases just as it lost the earlier ones.

To its credit, HHS states that “[i]n enforcing the nondiscrimination provisions in the corresponding CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. §§ 2000bb through 2000bb–4) and all other applicable legal requirements.” 87 Fed. Reg. at 597 (preamble). But this statement will come as cold comfort to stakeholders, particularly as the current Administration is actively appealing rulings of the district courts in *Franciscan Alliance* and *Sisters of Mercy*, where the religious organization plaintiffs prevailed under RFRA on substantially similar facts. Moreover, HHS recently revoked the authority that its own Office for Civil Rights had to ensure that HHS complies with RFRA.

In this light, where HHS can anticipate not only being sued under RFRA but also losing, the proposed rule itself should go further and include an exemption for those stakeholders with religious objections, which would include issuers, plan sponsors, and individual purchasers. In the absence of such an exemption and given the pending appeals, HHS’s mere assertion that it will “comply” with RFRA and other unspecified “applicable” laws essentially punts to the courts.

Conclusion

For all these reasons, we believe HHS should decline to include in the regulations language that is unnecessary to protect people from discrimination in receiving health care, and that could, instead, be construed to require coverage of procedures or treatments that health insurance issuers have determined are unsupported by medical evidence or that violate the religious and moral convictions of insurers, plan sponsors, and individual purchasers.

Thank you for the opportunity to comment.

Respectfully submitted,

Thomas Brejcha
President & Chief Counsel
Thomas More Society
Chicago, Illinois

David Nammo
Executive Director & CEO
Christian Legal Society

Anthony R. Picarello, Jr.
Associate General Secretary and General Counsel
Michael F. Moses
Director, Legal Affairs
Daniel E. Balsarak
Assistant General Counsel & Director fo
Religious Liberty
United States Conference of Catholic Bishops

(Signatures continued on next page.)

Ellen Gianoli, BSN, MA, RN
President
National Association of Catholic
Nurses, U.S.A.

Joseph Meaney, Ph.D.
President
The National Catholic Bioethics Center

Galen Carey
Vice President of Governmental Relations
National Association of Evangelicals