August 12, 2016

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3295-P
P.O. Box 8010
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, CMS-3295-P

Dear Sir or Madam:

On behalf of the Catholic Medical Association, National Catholic Bioethics Center, National Association of Catholic Nurses-U.S.A., Institutional Religious Freedom Alliance, National Association of Evangelicals, Ethics & Religious Liberty Commission of the Southern Baptist Convention, Christian Legal Society, Family Research Council, First Liberty Institute, Thomas More Society, and United States Conference of Catholic Bishops, we submit the following comments on proposed regulations, issued by the Centers for Medicare and Medicaid Services ("CMS"), updating requirements that hospitals must meet to participate in the Medicare and Medicaid programs. *See* 81 Fed. Reg. 39448 (June 16, 2016).

The proposed regulations would forbid discrimination on the bases of "sexual orientation" and "gender identity."[1] In these comments, we identify and discuss four problems relating to this prohibition.

The first concerns the statutory authority under which CMS claims to be promulgating the regulations.

The second concerns interpretations of the proposed prohibition that could interfere with a hospital's professional judgment about what procedures or services are ethical, medically appropriate, or in a patient's best interest.

The third concerns interpretations of the proposed prohibition that could compromise the health, safety, or privacy of other patients.

The fourth concerns the right of religiously affiliated hospitals to carry out their mission free from government coercion to violate their religious beliefs, a right safeguarded, sometimes with reference to particular procedures and sometimes in more general terms, in federal law.

Throughout these comments we use the term "discrimination" because that is the term CMS uses. As explained in more detail below, a person's sexual inclination, sexual conduct, and internal sense of maleness or femaleness (if that is what the terms sexual orientation and gender identity mean) ordinarily have no bearing on the appropriateness of a particular hospital procedure or treatment. That is true, as well, of many other characteristics and behaviors not addressed in these regulations. Our principal point, however, is that the terms sexual orientation and gender identity could be construed to interfere with a hospital's decision about what sort of care is appropriate, or to require action by the hospital that compromises the health, safety or privacy of patients. It is not "discrimination" when a hospital provides care it considers appropriate, declines to perform procedures destructive to patients' welfare and well-being, or declines to take actions that undermine the health, safety, and privacy of other patients.

1. Section 1557 of the Affordable Care Act does not authorize the proposed prohibition on discrimination based on gender identity; Section 1861(e)(9) of the Social Security Act does not authorize the proposed prohibition on discrimination based on sexual orientation in any circumstance where its application could compromise patient health and safety.

CMS states (81 Fed. Reg. at 39450-51) that its proposed prohibition on *gender identity* discrimination is based on Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. Section 1557 prohibits discrimination on the bases of sex and other specified categories, but says nothing about "gender identity." As we have discussed in previous HHS rulemaking, there is no indication that Congress intended in Section 1557 to prohibit discrimination based on gender

[1] Our use of these terms is intended to mirror what the proposed regulations actually say, not to suggest agreement with the government's understanding of human sexual difference or related issues. In Part 2 of this letter, we discuss problems inherent in the terms "sexual orientation" and "gender identity."

identity, however that term is construed, and we incorporate by reference a fuller treatment of this issue in previously-filed comments.[2]

CMS states (81 Fed. Reg. at 39451) that its proposed prohibition on *sexual orientation* discrimination is based on Section 1861(e)(9) of the Social Security Act, 42 U.S.C. § 1395x(e)(9). Section 1861(e)(9) provides that a hospital must meet such requirements "as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." CMS may not rely upon Section 1861(e)(9), a provision that by its plain terms is intended to *protect* patient health and safety, to impose any requirement that, as applied, would *compromise* patient health and safety.[3] Some interpretations of the proposed regulations, as we explain below, would have precisely the latter effect.

2. <u>CMS should clarify that its proposed regulations do not mandate the performance of any procedure or treatment that, in the hospital's professional judgment, is not ethical, medically indicated, or in the patient's best interest.</u>

The term "sexual orientation" is ambiguous. The American Psychological Association ("APA") has adopted no uniform definition of the term and, on the contrary, has ascribed to it various meanings: (a) "an enduring pattern of emotional, romantic, and/or sexual attractions to men, women, or both sexes," (b) a person's "sense of identity based on those attractions," (c) "related behaviors," or (d) "membership in a community of others who share those attractions." APA, *Answers to Your Questions: For a Better Understanding of Sexual Orientation & Homosexuality* (2008), <u>www.apa.org/topics/lgbt/orientation.pdf</u>. These definitions are not necessarily consistent with each other. For example, a person could have an enduring pattern of sexual attraction to those of the opposite or same sex without engaging in overt sexual acts, and likewise could engage in overt heterosexual or homosexual acts without an enduring or predominant inclination to do so. In more recent statements, the APA has expressed reservations about whether the term "sexual orientation" constitutes even a definable category. "[R]esearch has suggested," the APA noted in 2011, "that sexual orientation does not always appear in such definable categories and instead occurs on a continuum." APA, *Practice Guidelines for LGB Clients: Guidelines for Psychological Practice for Lesbian, Gay, and Bisexual Clients*, under "Introduction," Definition of Terms, <u>www.apa.org/pi/lgbt/resources/guidelines.aspx</u>; *see also* Diamond & Savin-Williams, "Gender and Sexual Identity," in HANDBOOK OF APPLIED DEVELOPMENT SCIENCE (Richard M. Lerner, *et al*., eds.) at 102 (concluding, in a 2003 study, that "[t]here is currently no scientific or popular consensus on the exact constellation of experiences that definitively 'qualify' an individual as lesbian, gay, or bisexual").

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[2] *See* <u>www.usccb.org/about/general-counsel/rulemaking/upload/Comments-Proposal-HHS-Reg-Nondiscrimination-Federally-Funded-Health.pdf</u>.

[3] This is equally true were Section 1395x(e)(9) to be cited as an alternative ground for the proposed rule's prohibition on gender identity discrimination. In other words, Section 1395x(e)(9) may not be asserted as a basis for any regulatory requirement or prohibition that would undermine patient health or safety.

The term "gender identity" is also ambiguous. It is often used to refer to an internal sense of maleness or femaleness that differs from one's biological sex. In the view of many in the medical community (and in our view as well), this is a psychological *condition* in need of *care*, not a category of *persons* in need of special legal *protection*. Considering that a person's biological sex is often relevant in medical matters (many disorders affect only men or women, or affect men and women differently), the concept that one must consider and act upon the sex with which an individual identifies, even when that is opposed to his or her biological sex, may actually be inimical to good medicine.

To be sure, a person's sexual inclination, sexual conduct, or internal sense of maleness or femaleness ordinarily have no bearing on the appropriateness of a particular hospital procedure or treatment. No hospital refuses (or should refuse) to treat a broken arm, congestive heart failure, complications from diabetes, suicidal depression, or any other injury or pathology because of a person's sexual inclination, sexual conduct, or internal sense of maleness or femaleness, any more than it denies (or should deny) treatment based on political affiliation, educational background, or any number of other characteristics.

Placing such ambiguous terms as "sexual orientation" and "gender identity" in the regulations, however, is problematic if those terms are construed to require the performance of procedures or the provision of treatment that the hospital, in the exercise of its professional judgment, finds not to be ethical, medically indicated or in the patient's best interest. For example, CMS should not require that a hospital accede to a patient's wish to surgically alter his or her genitalia or receive hormone therapy for the purpose of appearing to be a sex other than his or her biological sex, when the hospital has determined, either in an individual case or in all cases, that such procedures are not ethical, not medically indicated, or not in the patient's best interest. A hospital does not engage in "discrimination" when, for example, it performs a mastectomy or hysterectomy on a woman with breast or uterine cancer, respectively, but declines to perform such a procedure on a woman with perfectly healthy breasts or uterus who is seeking to have the appearance of a man.

Indeed, *CMS itself* has been unable to determine whether such procedures provide a benefit when sought for the purpose of taking on the appearance of the opposite sex. Just two weeks before issuing the current proposed regulations, CMS proposed that it not issue a National Coverage Determination on sex reassignment surgery[4] for Medicare beneficiaries with gender

[4] The term "sex reassignment surgery" is a misnomer. First, one is not "assigned" a sex, but is male or female from conception. Second, "[i]t is physiologically impossible to change a person's sex, since the sex of each individual is encoded in the genes—XX if female, XY if male. Surgery can only create the *appearance* of the other sex." Richard P. Fitzgibbons, M.D., Philip M. Sutton & Dale O'Leary, *The Psychopathology of "Sex Reassignment" Surgery: Assessing its Medical, Psychological, and Ethical Appropriateness*, NATIONAL CATHOLIC BIOETHICS QUARTERLY 97, 118 (Spring 2009); *see also* Paul R. McHugh, M.D., *Transgender Surgery Isn't the Solution: A Drastic Physical Change Doesn't Address Underlying Psycho-Social Troubles* (June 12, 2014) ("'Sex change' is biologically impossible. People who undergo sex-reassignment surgery do not change from men to women or vice versa."), at www.wsj.com/articles/paul-mchugh-transgender-surgery-isnt-the-solution-1402615120; American College of Pediatricians, *Gender Ideology Harms Children* (Mar. 21, 2016, updated Apr. 6, 2016) (stating that human beings are "conceived either male or female," and that "[p]eople who identify as 'feeling like the opposite

dysphoria, precisely because of the absence of conclusive evidence that such surgery benefits rather than harms patients. CMS, *Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (June 2, 2016), at www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=282.[5] "Based on a thorough review of the clinical evidence available at this time," CMS wrote, "*there is not enough evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria*." *Id*. (emphasis added). "There were conflicting (inconsistent) study results—of the best designed studies, some reported benefits *while others reported harms*." *Id*. (emphasis added).

A hospital can reasonably conclude that sex reassignment surgery as a rule is not medically appropriate (or even ethical). Psychiatrist Richard P. Fitzgibbons and his colleagues give five reasons why this is so. First, such surgery "mutilates a healthy, non-diseased body" in violation of the principle, binding on health professionals, to "do no harm." *The Psychopathology of "Sex Reassignment" Surgery*, note 4 *supra*, at 97 (abstract). Second, the belief that one is trapped in the body of the wrong sex "is generated by a disordered perception of self. Such a fixed, irrational belief is appropriately described as a delusion." *Id*.[6] Third, sex reassignment surgery is a "category mistake" in that it "offers a surgical solution for psychological problems…." *Id*. at 97-98. Fourth, such surgery "does not change a person's sex; therefore, it provides no true benefit." *Id*. at 98. Fifth, such a procedure "is a 'permanent,' effectively unchangeable, and often unsatisfying surgical attempt to change what may be only a temporary (i.e., psychotherapeutically changeable) psychological/psychiatric condition." *Id*.

Research findings suggest poor outcomes for sex reassignment surgery. Tracking patients over a 30-year period, a study by the Karolinska Institute in Sweden "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."[7] A report from the Williams Institute of

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sex' or 'somewhere in between' do not comprise a third sex" but "remain biological men or biological women"), at www.acpeds.org/the-college-speaks/position-statements/gender-ideology-harms-children.

[5] CMS develops National Coverage Determinations "to describe the circumstances for Medicare coverage nationwide for an item or service. NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under § 1862(a)(1) of the [Social Security] Act or other applicable provisions of the Act." Medicare Program Integrity Manual, 13.1.1 (2013), at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

[6] To describe such beliefs as irrational or delusional is not to disparage persons who hold to such beliefs, but to recognize that their self-conception or understanding of the world in a critical respect does not conform to reality, a necessary first step in providing care for such persons.

[7] McHugh, *Transgender Surgery Isn't the Solution*, note 4 *supra*; *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."), at www.ncbi.nlm.nih.gov/pmc/articles/PMC3043071/pdf/pone.0016885.pdf; *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

UCLA likewise showed very high rates of suicide attempts in those who are "transgender." Ann P. Haas, *et al*., *Suicide Attempts among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey* (Jan. 2014), at http://williamsinstitute.law.ucla.edu/wp-content/uploads/AFSP-Williams-Suicide-Report-Final.pdf. Elsewhere Dr. Haas and her colleagues write—

> [An] international review of studies that followed over 2,000 persons in 13 countries who had undergone gender reassignment surgery identified 16 possible suicide deaths (Pfafflin & Junge, 1998). If confirmed as actual suicides, these figures would translate to an alarmingly high rate of 800 suicides for every 100,000 post-surgery transsexuals. By contrast, the current suicide rate for the overall U.S. population is 11.5 suicides per 100,000 people.

Haas, *et al*., *Suicide and Suicide Risk in Lesbian, Gay, Bisexual, and Transgender Populations: Review and Recommendation*, 58 J. of Homosexuality 10, 26-27 (Jan. 2011), at www.ncbi.nlm.nih.gov/pmc/articles/PMC3662085/. Still another study, following up with over 50 people who had undergone sex reassignment surgery 15 years earlier, found that on a number of measures, these persons were not experiencing benefits. Annette Kuhn, M.D., *et al*., *Quality of Life 15 Years after Sex Reassignment Surgery for Transsexualism*, 92 Fertility and Sterility 1685 (Nov. 2009), at www.fertstert.org/article/S0015-0282(08)03838-7/fulltext.

Hormone treatment also poses risks. Puberty-delaying hormones administered to children to facilitate later sex-change surgery "stunt[s] [their] growth and risk[s] causing sterility." McHugh, *Transgender Surgery Isn't the Solution*, note 4 *supra*. "Children who use puberty blockers to impersonate the opposite sex will require cross-sex hormones in late adolescence. Cross-sex hormones (testosterone and estrogen) are associated with dangerous health risks including but not limited to high blood pressure, blood clots, stroke and cancer." American College of Pediatricians, *Gender Ideology Harms Children*, note 4 *supra*, at 2.

By contrast, decisions *not* to provide hormonal or surgical interventions have yielded positive results. For example, Vanderbilt University and London's Portman Clinic found that a large percentage of children (70 to 80%) who reported transgender feelings but received no medical or surgical intervention ultimately lost those feelings. McHugh, *Transgender Surgery Isn't the Solution*, note 4 *supra*. The Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders ("DSM-V") reports an even higher percentage. American College of Pediatricians, *Gender Ideology Harms Children*, at 2 ("According to the DSM-V, as many as 98% of gender confused boys and 88% of gender confused girls eventually accept their biological sex after passing through puberty."). "What compassionate and reasonable person," the American College of Pediatricians asks, "would condemn young children to this fate [using cross-sex hormones and undergoing sex reassignment surgery] knowing that after puberty as many as 88% of girls and 98% of boys will eventually accept reality and achieve a state of mental and physical health?" *Id*. The American College of Pediatricians concludes that

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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), www.theguardian.com/society/2004/jul/30/health.mentalhealth.

"[c]onditioning children into believing that a lifetime of chemical and surgical impersonation of the opposite sex is normal and healthful is child abuse." *Id.*

No hospital should be required to perform a procedure or provide a treatment that is ethically questionable or potentially harmful to patients. Section 1861(e)(9) authorizes the Secretary only to impose requirements that are necessary to further the health and safety of patients. Therefore, if it retains the references to sexual orientation and gender identity in the regulations, CMS should clarify that nothing in the regulations should be construed to require a hospital to perform a procedure or provide a treatment if, in the hospital's professional judgment, it is unethical, not medically indicated, or contrary to the best interest of the patient.

3. <u>CMS should clarify that its proposed regulations do not require that patients of one biological sex be given access to services, procedures, or facilities if it could compromise the health, safety, or privacy of others.</u>

Being a biological male or female has important consequences in the delivery of health services because such services pertain to the health of the human *body*, and male and female bodies are different. Just as a hospital may, for the sake of patient privacy or for therapeutic reasons, lawfully consider an applicant's or employee's sex in making employment decisions,[8] a patient's biological sex is often relevant and properly considered in the delivery of health services. Patients have the right to bodily privacy, especially in such places as a hospital, where they are inherently exposed and vulnerable.

Likewise, some health care services are more effective when provided to persons of the same sex. For example, a hospital offering group therapy sessions to women should not be required to admit as a patient into those sessions an individual who is male but claims to have the internal sense of being female. This is especially important when, for example, the therapy is a response to domestic abuse or sexual violence perpetrated by men. Otherwise therapeutic outcomes that are achieved by limiting such sessions to biological women could be compromised. Similar examples can be posited for treatments or services provided to men (*e.g.*, group sessions to address medical problems that only men experience). This is not to suggest that anyone should be denied health care, but rather that medical professionals, for all of their patients, should retain the discretion to take the most appropriate and effective approach for treatment and placement in the various circumstances that may arise.

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[8] *See, e.g.*, *Healey* v. *Southwood Psychiatric Hosp.*, 78 F.3d 128 (3d Cir. 1996) (assigning female child care specialist to night shift was not unlawful because the presence of both males and females on all shifts was necessary to meet the therapeutic and privacy needs of a mixed-sex patient population of children and adolescents in a psychiatric hospital); *Jones* v. *Hinds Gen. Hosp.*, 666 F. Supp. 933 (S.D. Miss. 1987) (male patients in a hospital have a right to a hospital orderly who is male); *Local 567* v. *Michigan Council*, 635 F. Supp. 1010 (E.D. Mich. 1986) (patients in a state mental hospital have a right to a personal hygiene aide of the same sex); *see also Backus* v. *Baptist Med. Ctr.*, 510 F. Supp. 1191 (E.D. Ark. 1981) (ob-gyn patients have a privacy right to an obstetrical nurse who is female), *vacated as moot*, 671 F.2d 1100 (8th Cir. 1982); *Fesel* v. *Masonic Home of Delaware*, 447 F. Supp. 1346 (D. Del. 1978) (female residents of a retirement home have a right to a nursing aide who is female). In each of the cited cases, patient privacy interests prevailed over a claim of sex discrimination.

Nothing in Section 1861(e)(9) authorizes CMS to impose requirements that undermine the health, safety, or privacy of patients. If it retains the references to sexual orientation and gender identity in the regulations, CMS should clarify that the regulations do not require patients be given access to services, procedures, or facilities if it would compromise the health, safety or privacy of others.

4. <u>CMS should confirm that the proposed regulatory provisions regarding sexual orientation and gender identity do not apply to a hospital when their application would violate the hospital's religious beliefs or moral convictions.</u>

The Church Amendment protects the right of institutional and individual health care providers, on religious or moral grounds, not to perform sterilization procedures. 42 U.S.C. § 300a-7. Sex reassignment surgery is de facto sterilization because it renders the person who undergoes it permanently infertile.[9] To avoid a conflict with the Church Amendment, CMS should clarify that its regulations do not require hospitals to perform or participate in such procedures when they have religious or moral objections.

The Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §§ 2000bb *et seq*., is also applicable. Under RFRA, the government may not substantially burden a hospital's religious beliefs except to further a compelling interest, and then only by means least restrictive of religious liberty. We do not believe that the government can demonstrate a compelling interest in forcing hospitals to perform sex reassignment surgery or other procedures or treatments designed to enable men to present themselves as women, or to enable women to present themselves as men. Likewise, in a situation where a religiously affiliated hospital offers treatment or care aimed at improving marital relationships, such as marriage counseling, we do not believe that the government can demonstrate a compelling interest in requiring the hospital to provide such treatment or care to same-sex couples when it would violate the hospital's religious convictions with regard to marriage. To decline to provide marriage counseling in such circumstances is not an act of animus against persons in same-sex relationships, but a simple reflection of the hospital's beliefs about what marriage is.[10]

For these reasons, if it retains references to sexual orientation and gender identity in the final regulations, CMS should clarify that the regulations do not apply to a hospital when its application to the hospital would violate its religious or moral convictions.

<u>Conclusion</u>

One solution to the problems identified in this letter is simply to delete the regulatory references to "sexual orientation" and "gender identity." Given the lack of statutory authority for the inclusion of gender identity, the ambiguity of both terms, and the risk of compromising patient health, safety, and privacy, the deletion of those terms is, in our view, the best course and

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[9] Fitzgibbons, *et al*., *The Psychopathology of "Sex Reassignment Surgery*," note 4 *supra*, at 99.

[10] Of course, it is of no benefit to anyone, including patients, to force a counseling relationship where the counselor's and patients' presuppositions about marriage are so radically at odds.

the one we recommend. If, however, CMS rejects this recommendation, then, at a minimum, it should clarify what these terms mean and, in addition, should modify the proposed regulations by adding the following new provisions:

> *(a) Nothing in this Part shall be construed to require a hospital to perform a procedure or provide a treatment that, in the hospital's professional judgment, is unethical, not medically indicated, or contrary to the best interest of the patient.*
>
> *(b) Nothing in this Part shall be construed to require a hospital to perform a procedure, provide a treatment, or provide access to facilities that, in the hospital's professional judgment, could compromise the health, safety, or privacy of other patients.*
>
> *(c) The provisions of this Part pertaining to sexual orientation and gender identity (Sections 482.13(i) and 485.635(g)) shall not apply to a hospital if its application would violate the hospital's religious beliefs or moral convictions.*

The italicized language is critical to ensure that the regulations are not construed to prevent or impede hospitals from providing appropriate care to their patients, and to ensure compliance with the Church Amendment and RFRA. Absent these changes, we believe the regulations will not survive a legal challenge. *See* 5 U.S.C. § 706 (authorizing a court to "hold unlawful and set aside agency action[s]" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"); 42 U.S.C. § 2000bb-1 (authorizing judicial relief against the government for action that substantially burdens religious exercise if the action does not further a compelling interest by means least restrictive of religion).

Thank you for your careful attention to these comments.

Respectfully submitted,

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