Congress of the United States

Washington, DC 20515

October 6, 2016

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

We write to express a number of significant concerns regarding a final rule that went into effect on July 18, 2016: Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375 (May 18, 2016) (to be codified at 45 C.F.R. pt. 92).

First, this rule for the first time in history requires doctors to perform gender transition procedures or treatments on patients including children, even if the doctor believes the procedures could be harmful. 81 Fed. Reg. 31445. Doctors who follow their oath to act in the best interest of the patients by refusing to perform these procedures face massive financial penalties and even job loss. Never before has the federal government forced doctors to choose between caring for their patients based on their best medical judgment, and complying with federal law.

The very guidance cited by HHS to justify this rule includes studies showing that up to ninety-four percent of children who wrestle with gender dysphoria will outgrow the dysphoria naturally and become comfortable in the bodies they were born with. Children are some of the most vulnerable in our population, and this rule strips doctors of their ability to counsel and advise the best course of medical care in their professional judgment if they believe gender transition procedures to be harmful.

Second, HHS's own experts have acknowledged that the clinical literature is "inconclusive" on whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria, and that some studies have "reported harms."[1] As a result, HHS has

[1] Centers for Medicare & Medicaid Services, Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (GAG-00446N) (June 2, 2016), https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=282 ("Based on a thorough review of the clinical evidence available at this time, there is not enough evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria. There were conflicting (inconsistent) study results—of the best designed studies, some reported benefits while others reported harms.").

exempted Medicare and Medicaid from compliance with this coverage mandate, even while it requires virtually every *private* physician, healthcare provider, and health insurance plan in the country to do otherwise.

Third, in other contexts where the government requires services related to gender transition procedures, the government has clearly protected the medical judgment and moral or religious beliefs of healthcare professionals. For instance, a recent TRICARE guidance memo states in the context of gender dysphoria treatment, "In no circumstance will a provider be required to deliver care that he or she feels unprepared to provide either by lack of clinical skill or due to ethical, moral, or religious beliefs."[2] Yet no similar protections for physicians' medical judgment or beliefs are offered under HHS's rule. In fact, HHS specifically rejected multiple requests to include similar protections.

Fourth, the number of doctors and healthcare providers covered by this rule is breathtaking. By HHS's own estimation, this rule will "likely cover almost all licensed physicians," which you estimate as totaling over 900,000. *See* 81 Fed. Reg. 31445-31446. This rule will also apply to virtually all hospitals, nursing homes, and health insurers, and many educational institutions of higher learning with health programs as well.

Finally, the rule purports to prohibit discrimination on the basis of "termination of pregnancy." HHS received numerous requests to provide clarification as to whether prohibitions on sex discrimination could be construed to require insurance plans to cover abortion or require healthcare professionals to provide one contrary to their religious or moral beliefs. 81 Fed. Reg. 81387-31388. Despite these requests, the final rule offers no such assurances that these individuals and organizations will not be penalized for providing quality care or insurance coverage that excludes abortion services.

Because of the numerous and weighty concerns raised by this rule, we request the following information by November 14, 2016:

1. Assume a doctor's individual practice is a covered entity under the rule, and the doctor prescribes puberty blocking medication to children with a medical condition known as precocious puberty. Would that doctor be required under the rule to prescribe puberty blocking medication to children who have been diagnosed by a mental health professional as requiring puberty blocking medication to treat gender dysphoria, even if the doctor's best medical judgment was that such treatments are always experimental and inappropriate to provide to children to facilitate a gender transition?

2. Assume a doctor's individual practice is a covered entity, and the doctor regularly provides hysterectomies to women to treat uterine cancer. Would the doctor be required under the rule to provide a hysterectomy to treat gender dysphoria if the patient's mental

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[2] Memorandum from Karen S. Guice, Acting Assistant Sec'y of Defense to Assistant Sec'y of the Army, et al., Subject: Guidance for Treatment of Gender Dysphoria for Active and Reserve Component Service Members (July 29, 2016) ("Memorandum from Karen S. Guice").

health physician determined that a hysterectomy was medically necessary to treat gender dysphoria? Would the doctor be required to perform these procedures even if the doctor had ethical and religious objections to performing a hysterectomy to facilitate a gender transition?

3. In the context of the military's TRICARE health plan, a guidance memo regarding treatment of gender dysphoria states that "in no circumstance will a provider be required to deliver care that he or she feels unprepared to provide either by lack of clinical skill or due to ethical, moral, or religious beliefs."[3] Please explain in concrete detail why the Department's final rule does not provide similar protection for the clinical limitations, or ethical, moral, or religious beliefs of covered entities?

4. Your responses state in the context of services for "children" that "arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age." 81 Fed. Reg. 31408. Does this mean that physicians who are covered entities and who are unwilling to perform gender transition procedures on children under 18 could be subject to liability under the rule if they perform similar procedures on children under 18 for other medical reasons?

5. Assume a hospital is a covered entity and regularly provides hysterectomies to women to treat uterine cancer. Would the hospital be required under the rule to provide a hysterectomy to treat gender dysphoria if the patient's mental health physician determined that a hysterectomy was medically necessary to treat gender dysphoria? To take another example, assume a covered entity hospital employs a physician who performs hysterectomies for women with cancer but who is medically, ethically, or religiously opposed to ever performing a hysterectomy to facilitate a gender transition. Would that hospital face any liability under the rule if it accommodated the medical judgment, ethical concerns, or religious beliefs of its employed physician and allowed the physician to decline to perform a hysterectomy to facilitate a gender transition?

6. Does HHS provide a formal administrative process whereby covered entities with religious objections to the rule can prospectively seek a religious accommodation? If so, what is that process?

7. The rule prohibits discrimination on the basis of "termination of pregnancy." Please explain in concrete terms how this will apply to health insurance plans. For example, if an insurance plan of a covered entity covers dilation and evacuation (D&E) after a miscarriage to prevent infection, must the insurance plan also cover D&E for an abortion? Similarly, please explain in concrete terms how this will apply to a physician or hospital that is a covered entity. If a physician or hospital that is a covered entity performs D&E after a miscarriage to prevent infection, must the physician or hospital also perform D&E for an abortion?

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[3] Memorandum from Karen S. Guice, *supra*.

8. The rule states that "a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment." 81 Fed. Reg. 31406. Please provide concrete examples of other speech on the part of physicians or healthcare providers that could rise to the level of creating a hostile environment.

9. The rule states that "categorizing all transition-related treatment as cosmetic or experimental . . . . is now recognized as outdated and not based on current standards of care." 81 Fed. Reg. 31429. Please explain in concrete terms what this statement about standards of care means for healthcare providers. For example, if a covered entity counsels a patient that undergoing cross-hormone therapy or gender reassignment surgery is experimental in all instances, does the entity face any risk of liability under the regulation? If a doctor who prescribes puberty blocker medication to children with precocious puberty expresses the view that prescribing puberty blocker medication to children diagnosed with gender dysphoria is categorically experimental, will the doctor face liability under the rule if the doctor is a covered entity?

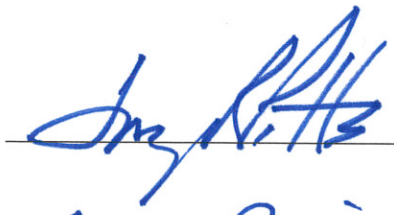
10. The rule cites approvingly (at footnote 263) to three publications on medical standards of care for transgender individuals. 81 Fed. Reg. 31435 n.263. Does the Department or its rule endorse these publications as setting forth the appropriate medical standards of care physicians should follow? If not, how are physicians to determine what the Department and the rule will use to determine the appropriate standard of care?

11. Please describe HHS's compelling governmental interest in promulgating this regulation, specifically with respect to prohibiting discrimination on the basis of "gender identity" and "termination of pregnancy." What are the key goals it is trying to accomplish?

12. In the Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N), medical experts at CMS recognized that some studies of gender reassignment surgery "reported harms," and that the clinical evidence was inconclusive on whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria. CMS therefore declined to issue a National Coverage Determination that would require coverage of gender reassignment surgery for Medicare beneficiaries—a decision that recently became final. Please explain the Department's rationale for applying different rules to Medicare and private insurance plans, and for requiring private doctors and hospitals that are covered entities to perform procedures that CMS has acknowledged could be harmful (assuming these doctors and hospitals perform similar procedures for other medical purposes).

If you have questions about this issue, please contact Kelley McLean with Congressman Joseph Pitts. Thank you for your prompt attention to this serious matter.

Sincerely,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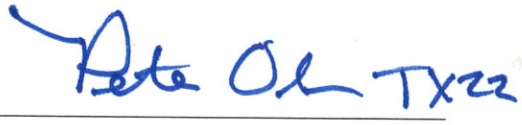
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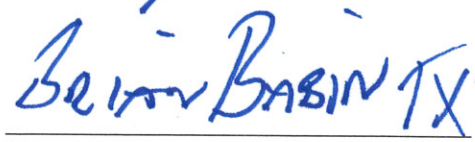
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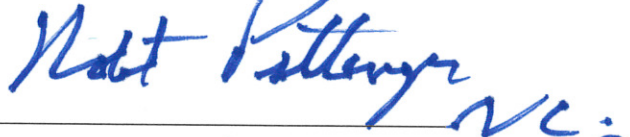
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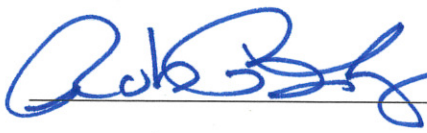
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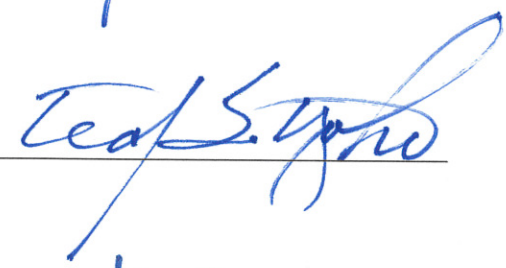

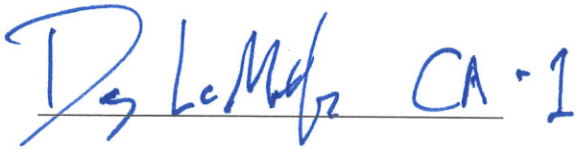
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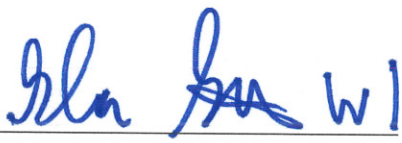
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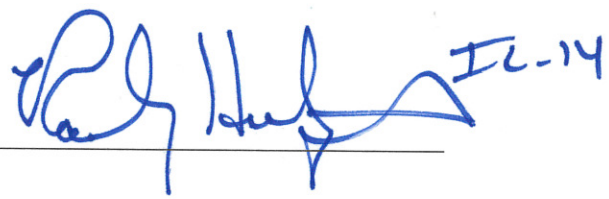
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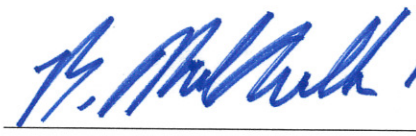
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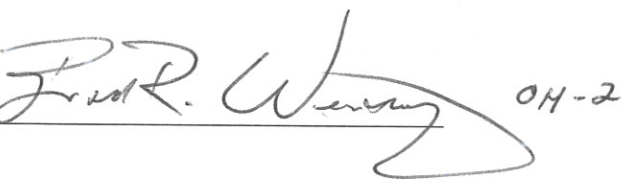
Randy K. Weber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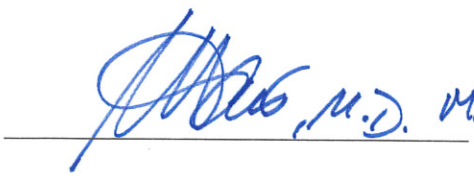
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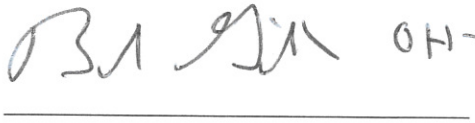
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