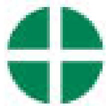
United States
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Submitted Electronically

October 2, 2024

U.S. Department of Health & Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

Subj: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule, RIN 0955-AA06

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (USCCB), we respectfully submit the following comments on the proposed rule, published by the Department of Health and Human Services at 89 Fed. Reg. 63498 (Aug. 5, 2024), in the above-captioned matter.

The proposed rule overall aims to strengthen health care for patients by improving electronic records and information sharing and interoperability. On behalf of the USCCB, we comment on two specific elements of the proposed regulations.

First, portions of the proposed regulations, if adopted, could impede access to information relating to "reproductive health care," including abortion, which would have the effect of deterring civil and criminal investigations into violations of state and federal law relating to abortion and other procedures. We oppose these aspects of the proposed rule and urge HHS not to adopt the rule as written insofar as it specifically relates to or contemplates "reproductive health care." Second, we oppose the standardization of terminology relating to "sexual orientation," "gender identity," and the use of "pronouns" in medical health records, and urge HHS to refrain from arbitrary classifications on this basis.

Discussion

In 2016, Congress enacted the 21st Century Cures Act. Pub. L. 114-255 (Dec. 13, 2016). Title IV of the Act promotes access to and use of electronic health information (EHI) by forbidding health care providers and other specified actors to block access to EHI. The Act, as HHS acknowledges, makes sharing EHI the "expected norm in health care." HHS, Office of the National Coordinator for Health Information Technology, Health IT.gov, _Information Blocking_. By the same token, the

Act authorizes the Department to create exceptions to this norm by identifying "reasonable and necessary activities" that do not constitute information blocking. 42 U.S.C. § 300jj-52.

HHS now proposes to create an exception that would allow and effectively encourage information blocking for "reproductive health care," a term that the Department defines broadly to include abortion.[1] Under the proposed exception, a health care provider or other actor may block access to EHI "to reduce potential exposure to legal action" involving reproductive health care. 89 Fed. Reg. at 63804, proposed 45 C.F.R. 171.206. As elaborated in the proposed rule, an actor may block access to EHI if it has a "good faith belief" that the "[p]ersons seeking, obtaining, providing, or facilitating reproductive health care are at risk of being potentially exposed to legal action" as a consequence of the disclosed information. *Id*. The proposed regulation purports to concern only reproductive health care that is "lawful under the circumstances," but the care provided "is *presumed* to have been lawful" unless the actor has "actual knowledge that the care was *not* lawful." *Id.* (emphasis added). This is unusual because it entrusts to regulated entities, including those not subject to privacy rules under the Health Insurance Portability and Accountability Act (HIPAA), the task of determining, based on actual knowledge, the lawfulness of others' actions.

We recognize that the proposed regulation does not directly attempt to preempt obligations to share information under state law. The proposed regulatory exception, however, is of a piece with the Department's recently promulgated HIPAA regulations. The HIPAA regulations, as we and others cautioned when they were proposed,[2] have the effect of impeding the enforcement of state and even federal laws in cases involving abortion and other procedures. Indeed, for that reason, the finalized HIPAA regulations are now the subject of a pending court challenge. *Texas v. HHS*, No. 5:24-cv-00204 (N.D. Tex.) (filed Sept. 4, 2024).

The effect of the Department's focus on "reproductive health care" in both the HIPAA regulations[3] and the regulations proposed in this current round of rulemaking, taken together, is to make it more difficult to enforce civil and criminal laws applicable to abortion providers, including state laws

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[1] 89 Fed. Reg. at 63802, proposed 45 C.F.R. § 171.102 (defining "reproductive health care" to have the same meaning as in 45 C.F.R. § 160.103, which in turn defines "reproductive health care" to mean "health care … that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes"). We use the term "reproductive health care" only because that is the term HHS uses. In fact, abortion is not health care because it intentionally takes a human life and therefore neither advances health nor constitutes care. Even those who regard abortion as health care acknowledge that abortion is nearly always elective. The vast majority of women undergoing an abortion do not even cite maternal health as the principal reason for the abortion. *See*, *e.g*., M. Antonia Biggs, Heather Gould, and Diana Greene Foster, *Understanding Why Women Seek Abortions in the US*, BMC WOMEN'S HEALTH, 13:29 (2013) (6% citing their own concern for their physical or mental health as a reason); Aida Torres and Jacqueline Darroch Forrest, *Why Do Women Have Abortions?*, 20 FAM. PLANNING PERSPECTIVES 169 (1988) (only 3% cited health as the principal reason for having their abortion).

[2] *See* Comments dated June 12, 2023, of USCCB. S*ee also* Comments dated June 16, 2023, of the Mississippi Attorney General and the Attorneys General of 18 other states.

[3] Published at 89 Fed. Reg. 32976 (Apr. 26, 2024).

that are validly enacted under the states' police power.[4] Indeed, as its motivation for the proposed rule, HHS cites *Dobbs v. Jackson Women's Health Org*., 597 U.S. 215 (2022), which overturned *Roe v. Wade*, 410 U.S. 113 (1973), and recognized the authority of the People, through their elected representatives, to pass laws regulating and even prohibiting abortion. 89 Fed. Reg. at 63622, 63627. As we and others have noted, *see* n.2 *supra*, states have an important interest in regulating providers who perform abortion and in seeing that state laws in this area are enforced, an interest that *Dobbs* vindicates. The proposed rule, if adopted, will further impede access to information needed to enforce such laws.

The federal government has no general police power to regulate medicine. Any federal proposal that compromises the enforcement of state law whenever it happens to involve an abortion fails to be "reasonable and necessary" as required by the authorizing statute and is arbitrary and capricious in violation of the Administrative Procedure Act.

Importantly, these aspects of the proposed rule would make it difficult to enforce not only state abortion prohibitions, but countless state laws designed to protect the lives and health of women, such as requirements pertaining to informed consent and parental notification, or even laws against abuse or trafficking, including in cases where the abortion itself is lawful. And because HHS defines "reproductive health care" broadly to mean health care that affects the health of an individual in all matters relating to the reproductive system and its functions and processes, *see* n.1 *supra*, the problems we have noted with respect to abortion would similarly affect the enforcement of federal and state laws regulating contraceptives, sterilization, and "gender-related procedures." For example, the proposed regulations would seem to impede investigations into possible violations of federal informed consent requirements set forth in 42 C.F.R. § 50.204 with respect to sterilization, and comparable state law requirements.

There may be (in fact, there often will be) a dispute over whether any particular abortion is lawful or not. It should not be "presumed" that an abortion is lawful, as these proposed regulations would do. 89 Fed. Reg. at 63804, proposed 45 C.F.R. 171.206. In most cases, it cannot be known, *prior* to investigation, whether a particular abortion is lawful or not. Information may be sought in criminal, civil, and administrative proceedings for the very purpose of determining whether the procedure was lawful. The proposed rule therefore creates a Catch 22 by impeding access to information needed to make that determination. It also places regulated entities in the peculiar and burdensome role of having to assess the legality of others' actions.

HHS further proposes to adopt updated terminology for coding in EHI as it relates to "sexual orientation," "gender identity," and the usage of "pronouns." Underlying these classifications is the premise that a patient's sexual identity is radically separated from its objective basis, rooted in his or her biological sex as male and female. According to the Department, the standardization of

[4] *See* 89 Fed. Reg. at 63627 (citing, as a rationale for the rule, "[f]ear of being investigated or of having to defend [oneself] against potential legal lability" under laws authorizing administrative, civil, or criminal actions in relation to abortion).

data on sexual orientation and gender identity (SOGI) in medical health records "will provide additional insight on trends in hospitalization, surveillance of symptomology and diagnoses, and demographics that can highlight disparities and better inform interventions." 89 Fed. Reg. at 63546, 63711 (preamble). In effect, the proposed rule incorporates a new norm relating to data collection, laying the foundation for an approach to medical records that is not authentically evidence-based and potentially forming the impetus for patients to receive medically harmful interventions. Indeed, these arbitrary classifications in the proposed rule are surprising given that the federal government has acknowledged in its own reports on SOGI data collection that "SOGI terminology is fluid and continues to evolve over time."[5] We therefore urge HHS to exercise caution and refrain from incorporating such terminology in coding for EHI.

Conclusion

In our view, the proposed exception for "reproductive health care" from information blocking regulations is unreasonable, unnecessary, arbitrary and capricious, an abuse of discretion, and contrary to law because it has the effect of impeding investigations into violations of federal and state law relating to reproductive health care. We urge HHS not to adopt the exception. The federal government has no legitimate interest in impeding the enforcement of such laws. Nor does the federal government have a legitimate interest in the collection of data based on self-classifications of "sexual orientation and gender identity," especially when it has recognized that such terminology continues to evolve and thereby evades objective standardization.

Respectfully submitted,

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[5] Federal Committee on Statistical Methodology, "Updates on Terminology of Sexual Orientation and Gender Identity Survey Measures," August 2020, 21, available at https://www.fcsm.gov/assets/files/docs/FCSM_SOGI_Terminology_FY20_Report_FINAL.pdf. *See also* Subcommittee on Sexual Orientation, Gender Identity, and Variations in Sex Characteristics (SOGI) Data: Subcommittee on Equitable Data of the National Science and Technology Council, "Federal Evidence Agenda on LGBTQI+ Equity," January 2023, available at https://www.whitehouse.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf.