ETHICS AND PUBLIC POLICY CENTER

October 4, 2024

Via Federal eRulemaking Portal

Micki Tripathi, PhD.
Assistant Secretary for Technology Policy and National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: EPPC Scholars Comment Opposing "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule," RIN 0955-AA06

Dear Assistant Secretary Tripathi:

My name is Eric Kniffin. I am a scholar at the Ethics and Public Policy Center (EPPC) and a member of EPPC's HHS Accountability Project. I have also served as an attorney in the U.S. Department of Justice's Civil Rights Division. I write today in opposition to selected aspects of the Department of Health and Human Services' ("HHS") Proposed Rule "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule" ("Proposed Rule").[1]

My comments focus on two aspects of the Proposed Rule. First, the Proposed Rule would standardize terminology related to "sexual orientation," "gender identity," and the use of "pronouns" in medical health records. HHS has not explained or justified its efforts to impose these classifications on health providers and I urge HHS to refrain from arbitrary classifications on this basis. Second, the Proposed Rule creates new exceptions to Congress' rules against information blocking that build on the Department's deeply flawed and unlawful HIPAA Privacy Rule, finalized earlier this year. These new provisions continue the Department's efforts to undermine the rule of law by creating special rules that apply only to "reproductive health care" in order to advance the administration's pro-abortion and pro-"gender transition" agenda, an agenda that the American people do not share.

I opposed these aspects first and foremost because I believe they are contrary to HHS's mission, which is "to enhance the health and well-being of all Americans."[2] As I and my colleagues at EPPC's HHS Accountability Project have stated in other public comments, this administration's unyielding commitment to gender ideology and to abortion are contrary to human flourishing. For example, last year we said the following in a public comment stating "our general opposition to the Department's efforts to promote and normalize gender ideology":

[1] 89 Fed. Reg. 63,498 (Aug. 5, 2024).
[2] HHS, *Introduction: About HHS*, https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html.

> All persons are made in the image and likeness of God, and as such, all people have immeasurable dignity. Recognizing the dignity in another, however, does not require that one endorse that person's choices. It does not require that one endorse what that person believes about himself or herself or that one gives another person what that person asks for.
>
> Indeed, loving and respecting another person requires telling the truth, even when that truth may be hard to hear. . . . [A] person's sex is defined as "male or female according to their reproductive organs and functions assigned by the chromosomal complement." Sex is imprinted in every cell of the person's body and cannot change. EPPC scholars have produced extensive materials and advocacy to support the fundamental biological truths of human sexuality in many different areas, especially law and policy. [3]

Likewise, EPPC recognizes the humanity and the dignity of the unborn life that is targeted for destruction in every abortion procedure.

The purpose of this public comment is not merely to note my disagreement with the administration's anthropology but also to make a record regarding the Proposed Rule's many and serious flaws. For the reasons stated below, the Department should abandon and withdraw the identified aspects of the Proposed Rule.

I. The Proposed Rule would introduce new categories for "sexual orientation," gender information" and "pronouns."

The first aspect of the Proposed Rule I wish to address is its new standards for coding EHI using taxonomy that reflects gender ideology. HHS's proposed update to §170.207 states that sexual orientation must be coded in accordance with at least one of the following codes:

(i) *Lesbian, gay, or homosexual.* 38628009
(ii) *Straight or heterosexual.* 20430005
(iii) *Bisexual.* 42035005
(iv) *Something else, please describe.* NullFlavor OTH
(v) *Don't know.* NullFlavor UNK
(vi) *Choose not to disclose.* NullFlavor ASKU

Id. at 63,769. The same section also states that gender identity must be coded in accordance with at least one of the following codes:

(i) *Male.* 446151000124109
(ii) *Female.* 446141000124107
(iii) *Female-to-Male (FTM)/Transgender Male/Trans Man.* 407377005
(iv) *Male-to-Female (MTF)/Transgender Female/Trans Woman.* 407376001
(v) *Genderqueer, neither exclusively male nor female.* 446131000124102
(vi) *Additional gender category or other, please specify.* NullFlavor OTH
(vii) *Choose not to disclose.* NullFlavor ASKU

[3] EPPC Scholars Comment Opposing HHS OCR's "Health and Human Services Grants Regulation," RIN 0945-AA19 (Sept. 11, 2023) (citations omitted), https://eppc.org/wp-content/uploads/2023/09/EPPC-Comment-Opposing-HHS-Grants-NPRM.pdf.

Id. Relatedly, HHS states that pronouns must be coded "in accordance with, at a minimum, at least one of the versions of LOINC codes specified in paragraph (c) of this section." *Id*. The relevant LOINC Code, 90778-2, includes the following sets of pronouns:

he/him/his/his/himself
she/her/her/hers/herself
they/them/their/theirs/themselves
ze/zir/zir/zirs/zirself
xie/hir ("here")/hir/hirs/hirself
co/co/cos/cos/coself
en/en/ens/ens/enself
ey/em/eir/eirs/emself
yo/yo/yos/yos/yoself
ve/vis/ver/ver/verself[4]

At the same time, however, HHS acknowledges that proper health care requires that providers record a patient's "birth sex." 89 Fed. Reg. at 63,769.

HHS does little in the Proposed Rule to justify imposing these new categories on covered entities as they record EHI. It merely states in the preamble, without citation, that recording sexual orientation and gender identity "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 63,546, 63,711.

Though HHS has emphasized in other context that health care should be "evidence based," it has done nothing here to justify imposing this terminology on our nation's medical system. Though a patient's sex (referred to in the Proposed Rule as "birth sex") is an objective fact that has obvious significance for providing medical care and interpreting a patient's chart, the same cannot be said about sexual orientation and gender identity information. As the federal government has acknowledged elsewhere, "SOGI terminology is fluid and continues to evolve over time."[5]

These proposals raise important questions that HHS should consider as it continues to work on these proposals and which it must address should it maintain its current course in a final rule:

- What criteria should a provider use when coding health information for sexual orientation, gender identity, or pronouns?
- What should a provider do if a patient expresses a gender identity or sexual orientation that does not clearly fit into one of the categories established by HHS?
- As noted above, the Proposed Rule does not reflect the reality that while an individuals' sex does not change, his or her sexual orientation, expressed gender identity, and preferred pronouns can change, and often do. What guidance does HHS offer covered entities about what to do when a patient changes his or her sexual orientation, expressed gender identity, or preferred pronouns?

[4] LOINC, *Code 90778-2, Personal pronouns – Reported*, v. 2.78, https://loinc.org/90778-2/ .
[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 .

- Is an entity expected or obligated to "update" health records when a patient changes how he or she identifies?

- What is the potential liability for covered entities that code information according to the patient's self-understanding at the time, but then fails to update these records at a patient's request?

- How do the data standards here reflect the present and growing reality of detransitioners, people who had once identified as transgender but then came to embrace their sexual identity?

- Will the categories introduced here make it harder for covered entities to collect data relevant to a given patient whose stated sexual orientation or gender identity or pronouns have changed across time?

- Will these new data standards make it easier for HHS or other bodies to collect and study data about how individuals' sexual orientation, gender identity, and preferred pronouns change over time?

- Will these new data standards make it easier for HHS or other bodies to collect and study data about people who detransition and embrace their biological sex?

- What potential actions may be taken against a covered entity or provider that operates within the taxonomies established by the Proposed Rule but declines to record a patient's self-declared sexual orientation, gender identity, or pronouns?

    - For example, what if a provider simply wrote "Don't know" for every patient's sexual orientation?

    - For example, what if a provider simply recorded the patient's "birth sex" as the patient's "gender identity"?

- To the extent that providers may have or may fear legal or professional consequences for failing to record a patient's current expressed sexual orientation, gender identity, or preferred pronouns, what steps will HHS take to affirm and defend providers' rights to freedom of speech, freedom of conscience, and freedom of religion?

II. The Proposed Rule sidesteps Congress' policy against information blocking to advance the administration's pro-abortion and pro-gender transition agenda.

The second aspect of the Proposed Rule I wish to address concern HHS's proposed adjustments to Congress's prohibition against information blocking. When Congress passed the 21st Century Cures Act in 2016, it made sharing electronic health information the expected norm in health care. Many had expressed concerns that some providers might engage in anti-competitive behavior by refusing to share EHI with outside providers, especially with competitor, prioritizing profits over the patient mobility the information sharing provision was supposed to promote.

In response, Congress created a general rule against information blocking: providers cannot "unreasonably limit the availability and use of EHI for authorized and permitted purposes." 42 U.S.C. § 300jj-52. Those that violate the information sharing rules may be subjected to hefty financial penalties, reputational harm, increased regulatory scrutiny, and litigation.

At the same time, Congress authorized the Secretary of HHS to identify "reasonable and necessary activities that do not constitute information blocking." 42 U.S.C. § 300jj-52(a)(3). To date, HHS has identified eight exceptions to the information sharing requirements, found in 45 C.F.R. Part 171. These exceptions have been stable and represent understandable, generally-applicable situations where public policy and patients' interests support exceptions from the general rule that Congress established.

The Proposed Rule also includes a new section §171.141, which lists helpful examples of the types of practices that constitute impermissible information blocking:

> (1) *Delay on new access.* Delaying patient access to new EHI, such as diagnostic testing results, so clinicians or other actor representatives can review the EHI.
>
> (2) *Portal access.* Delaying patient access to EHI in a portal when the actor has the EHI and the actor's system has the technical capability to support automated access, exchange, or use of the EHI via the portal.
>
> (3) *API access.* Delaying the access, exchange, or use of EHI to or by a third-party app designated and authorized by the patient, when there is a deployed application programming interface (API) able to support the access, exchange, or use of the EHI.
>
> (4) *Non-standard implementation.* Implementing health information technology in ways that are likely to restrict access, exchange, or use of EHI with respect to exporting electronic health information, including, but not limited to, exports for transitioning between health IT systems.
>
> (5) *Contract provisions.* Negotiating or enforcing a contract provision that restricts or limits otherwise lawful access, exchange, or use of EHI.
>
> (6) *Non-compete provisions in agreements.* Negotiating or enforcing a clause in any agreement that: (i) Prevents or restricts an employee (other than the actor's employees), a contractor, or a contractor's employee (ii) Who accesses, exchanges, or uses the EHI in the actor's health IT (iii) From accessing, exchanging, or using EHI in other health IT in order to design, develop, or upgrade such other health IT.
>
> (7) *Manner or content requested.* Improperly encouraging or inducing requestors to limit the scope, manner, or timing of EHI requested for access, exchange, or use.
>
> (8) *Medical images.* Requiring that the access, exchange, or use of any medical images (including, but not limited to, photograph, x-rays, and imaging scans) occur by exchanging physical copies or copies on physical media (such as thumb drive or DVD) when the actor and the requestor possess the technical capability to access, exchange, or use the images through fully electronic means.

Id. at 63,802-03. These examples reflect the same spirit as the exceptions that HHS has previously established in 45 C.F.R. Part 171. In each instance, HHS has honored Congress' general rule against information blocking. HHS is focused on creating general rules that apply across the board, applicable in a wide array of circumstances. None of these exceptions or examples give any hint that HHS has thought it appropriate to use its delegated authority from Congress to create special rules and protections for certain types of behavior.

This long track record is precisely what makes HHS's proposed changes to its information blocking regulations so unusual and arresting.

Expanding the existing "privacy exception." First, HHS proposed to expand the existing "privacy exception" found at 45 C.F.R. 171.202. At present, this "privacy exception" allows a covered entity to honor an individual's request that it not share its EHI, but this exception does not apply if the sharing of EHI is "otherwise required by law. 45 CFR §171.202(e).

The proposed rule suggests that this provision should be modified in light of *Dobbs* and subsequent state pro-life laws, which HHS says "have had far-reaching implications for health care beyond the effects on access to abortion." 89 Fed. Reg. at 63,622. HHS states it is concerned that covered actors might refuse to honor an individual's request for privacy regarding abortion-related EHI "due to uncertainty" regarding whether the actor has a legal obligation to cooperate with state efforts to enforce pro-life laws. *Id*.

To address this alleged problem, HHS proposed to revise the § 171.202(e) sub-exception. At present, this exception to the rule against information blocking is available *only* for individual-requested restrictions on EHI sharing that are permitted by other applicable law. But the Proposed Rule would loosen this requirement, allowing the blocking of information sharing even of applying restrictions the individual has requested on the access, exchange, or use of an individual's EHI even when the actor may have concern that another law applicable to some or all of the actor's operations could compel the actor to provide access, exchange, or use of EHI contrary to the individual's expressed wishes.

HHS summarizes the effect of its proposal as follows:

> [T]he proposed revision to § 171.202(e) would not operate to override other law compelling disclosure against the individual's wishes. It would, however, offer actors who elect to honor individual requested restrictions certainty that applying those restrictions will not be considered information blocking so long as the actor's practices in doing so satisfy the requirements of the § 171.202(e) subexception.

Id.

Adding a new "Protecting Care Access Exception." HHS also proposes to create a whole new ninth exception to Congress' rule against information blocking, a new a "Protecting Care Access Exception." Like the expansion of the "privacy exception" noted above, HHS claims that this change to the information blocking rule is necessary in light of *Dobbs* and the new HIPAA Privacy Rule.

HHS claims that *Dobbs* and subsequent state pro-life laws "increase[] the likelihood that a patient's EHI may be disclosed in ways that erode trust in health care providers and the health care system, ultimately chilling an individual's wiliness to seek, or other persons' willingness to provide or facilitate, lawful [reproductive] health care." *Id*. at 63,627. HHS says its proposed "Protecting Care Access Exception" to alleviate concerns that an actor may violate information blocking rules when "an actor believes in good faith" that sharing EHI "could risk exposing a patient, provider, or facilitator of lawful reproductive health care to potential legal action based on what care was sought, obtained, provided, [or] facilitated." *Id*. at 63,630.

As with the proposed expansion to the privacy exception, HHS states that it is merely broadening the exceptions to the information blocking rule; it is not attempting "to override any provision of another law that is independently applicable to the actor." *Id*. at 63,509.

Again, HHS's proposal raises a number of important questions HHS should consider as it continues to evaluate the Proposed Rule:

- HHS attempts to justify its proposed changes to its information blocking regulations by referencing its recent final rule amending the HIPAA Privacy Rule, 89 Fed Reg. 32,976 (April 24, 2024). For all the reasons we noted in our public comment on that rulemaking,[6] the HHS Accountability Project believes that the 2024 HIPAA Privacy Rule is unlawful.

- As the Department is aware, the State of Texas has already filed a lawsuit seeking declaratory and injunctive relief against enforcement of this final rule.[7]

    - Does HHS concede that the proposed changes to information blocking regulations will not be justified if and when federal courts find the 2024 HIPAA Privacy Rule unlawful?

    - If HHS does not so concede, on what basis, independent of the 2024 HIPAA Privacy Rule, would HHS claim that the proposed changes to information blocking regulations are justified?

- In our public comment on the HIPAA Privacy Rule, we noted that the proposed rule's definition of "reproductive health care" was so broad that it would also apply to gender transition procedures.[8] We asked HHS to confirm that reading in our public comment and also to explain the implications of that aspect of the proposed rule. HHS maintained these definitions in its final rule yet ignored our public comment asking for clarification on how the HIPAA Privacy Rule affects PHI related to gender transition procedures.

    - As the Proposed Rule builds on the HIPAA Privacy Rule, we renew these questions and ask HHS to clarify how the 2024 HIPAA Privacy Rule, and this Proposed Rule by extension, apply to gender transition procedures.

- While the preamble to the 2024 HIPAA Privacy Rule states clearly HHS's intent to frustrate legitimate law enforcement activity aimed at investigating potential violations of valid state pro-life laws, the rule also has implications for interactions between covered providers. For example, it is not uncommon for a woman after an abortion procedure to present herself to an emergency room or another provider for follow-up care.

    - Could an abortion provider use the 2024 HIPAA Privacy Act to refuse to share information with another medical provider that is providing post-abortion care? If so, under what circumstances would it be lawful or unlawful for the abortion provider to provide information to the post-abortion care provider?

    - Likewise, under the Proposed Rule, would an abortion provider violate HHS's rules against information blocking if it provided to respond to inquiries from another medical provider regarding the details of any abortion performed? Under what circumstances would it be lawful or unlawful for the abortion provider to refuse to share EHI with the provider providing post-abortion care?

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[6] EPPC Scholars Comment Opposing "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," RIN 0945-AA20 (June 13, 2023), https://eppc.org/wp-content/uploads/2023/07/EPPC-Scholars-Comment-Opposing-the-HIPAA-Privacy-Reproductive-Health-Care-NPRM.pdf.

[7] *See* Attorney General of Texas, *Attorney General Ken Paxton Sues Biden Administration Over Illegal Rule that Would Weaken State Law Enforcement and Investigation Authority* (Sept. 24, 2024), https://www.texasattorneygeneral.gov/news/releases/attorney-general-ken-paxton-sues-biden-administration-over-illegal-rule-would-weaken-state-law.

[8] EPPC Scholars Comment at 7.

CONCLUSION

For the reasons stated above, and for the reasons stated in the EPPC's public comment in opposition to the now-finalized 2024 HIPAA Privacy Rule, the aspects of the Proposed Rule are unlawful and are contrary to HHS's mission, "to enhance the health and well-being of all Americans."

I urge the Department to abandon and withdraw the identified aspects of the Proposed Rule.

Sincerely,

Eric Kniffin, J.D.
Fellow
HHS Accountability Project
Ethics & Public Policy Center