

June 16, 2023

Via Federal eRulemaking Portal

Xavier Becerra
Secretary
Attn: HIPAA Privacy Rulemaking
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: EPPC Scholars Comment Opposing “HIPAA Privacy Rule To Support Reproductive Health Care Privacy,” RIN 0945-AA20

Dear Secretary Becerra:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in strong opposition to the Department of Health and Human Services’ (“HHS”) Proposed Rule “HIPAA Privacy Rule To Support Reproductive Health Care Privacy” (“Proposed Rule”).¹

Eric Kniffin is an EPPC Fellow, member of EPPC’s HHS Accountability Project, and a former attorney in the U.S. Department of Justice’s Civil Rights Division. For more than a decade, Eric has represented plaintiffs seeking judicial relief from the Departments’ contraceptive mandate, as counsel for the Becket Fund and in private practice. Natalie Dodson is a Policy Analyst and member of EPPC’s HHS Accountability Project.

We offer this public comment to make a record regarding the Proposed Rule’s many and serious flaws. First, the Department has failed to establish a need for the Proposed Rule: its self-serving conjectures and its reliance on reaction pieces from last summer do not establish that the current Privacy Rule is causing “confusion.” Second, even if the current rule causes “confusion,” the Proposed Rule makes the Privacy Rule worse by introducing a number of critical terms that are either poorly defined or not defined at all. Third, the Proposed Rule will also create more confusion by greatly complicating the decision-making process a covered entity must undergo when deciding whether to use or disclose PHI.

But the Proposed Rule does not merely make the Privacy Rule more confusing and complicated. Covered entities must navigate this confusion knowing that HHS—the federal agency responsible for writing, finalizing, interpreting, implementing, and enforcing the Privacy Rule—is openly hostile to state efforts to protect unborn human life, protect minors from life-altering “gender transition” procedures, and other related state interests recognized by the Supreme Court in *Dobbs v. Jackson Women's Health Org.* Given the political content in the Proposed Rule, given the Department’s wide-ranging authority to interpret and enforce these vague rules, and given the considerable civil, criminal, and professional consequences that come with adverse HIPAA determination under the Privacy Rule, we fear that the Privacy Rule would chill health care professionals from cooperating with legal and legitimate state

¹ 88 Fed. Reg. at 23506.

activities that stem from their traditional police powers, which include promoting the public health, morals, or safety, and the general well-being of the community.

For all these reasons, The Department should abandon and withdraw the Proposed Rule.

I. HHS has failed to establish a need for the Proposed Rule.

Federal administrative agencies are required to engage in “reasoned decision making.”² This obligation requires a federal agency to identify the problem it intends to address.³ To justify replacing current regulations, an agency must provide specific evidence as to how the current regulations are causing harms or burdens and how the Proposed Rule would remedy the alleged defects *without* causing equal or greater harms and burdens.⁴ For this Proposed Rule, HHS has failed to meet that exacting standard in every respect. Specifically, HHS has failed to provide concrete evidence that the Privacy Rule as it currently exists has or will cause harm or burdens necessitating the need for this rulemaking and that the proposed regulations will remedy that harm.

A. The Proposed Rule asserts, but fails to establish, that the Supreme Court’s *Dobbs* decision has created a need for new rulemaking.

HHS’s justification for this Proposed Rule centers around the Supreme Court’s June 2022 decision in *Dobbs v. Jackson Women’s Health Org.*,⁵ which is referenced *nineteen times* in the preamble. Though the Proposed Rule was issued less than ten months after the *Dobbs* decision, HHS claims that it has already “carefully analyzed” the issue.⁶ However, the Proposed Rule’s preamble does not demonstrate any actual problem that needs to be solved.

Much of the Department’s supposed justification for the Proposed Rule is built on other groups’ short-term reactions to and unsupported claims about *Dobbs*’ impact. HHS cites a Consumer Reports piece published *the same day* as *Dobbs*,⁷ a JAMA Network article published *seven days* later,⁸ a New Yorker piece published *eight days* after *Dobbs* decision,⁹ and a blog post from the Federal Trade Commission released *twenty-one days* after *Dobbs*.¹⁰ HHS relies on *at least eleven other reports* published in the summer of 2022.¹¹

The Department also relies on a “recently filed complaint” where a plaintiff alleges that her health-care provider falsified medical records because of *Dobbs*.¹² Falsifying medical records is a felony under 18 U.S.C. § 1035 and remains such after *Dobbs*. It is not clear whether the HHS had this or other crimes in mind when the Proposed Rule states, without citation, that “[r]ecent state actions now place

² *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015).

³ EO 12866 § 1(b) (establishing the principles of regulation, including that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.”).

⁴ *Michigan*, 576 U.S. at 779 (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) (“a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist”).

⁵ 142 S. Ct. 2235 (2022).

⁶ 88 Fed. Reg. at 23510.

⁷ 88 Fed. Reg. at 23519 n.162.

⁸ *Id.*

⁹ 88 Fed. Reg. at 23509 n.25.

¹⁰ 88 Fed. Reg. at 23510 n.28.

¹¹ *See*, for example, 88 Fed. Reg. at 23519 nn. 163, 166, and 169, *id.* at 23520 nn. 171 and 174.

¹² 88 Fed. Reg. at 23519 and n.180.

individuals and health care providers in potential civil or criminal jeopardy when PHI related to an individual's reproductive health is used and disclosed."¹³ Nonetheless, it is difficult to understand how these alleged crimes justify the Proposed Rule.

The Department also relies on its own conjectures about *Dobbs*' impact. For example, HHS claims, "we **believe it may be necessary** to modify the Privacy Rule" to prevent people from seeking PHI "for a non-health care purpose where such use or disclosure would be detrimental to any person."¹⁴ HHS is likewise concerned about what actions state actors "**may attempt**" in their efforts to enforce state laws, and furthermore surmises that such law enforcement efforts are "**likely to chill** individuals' willingness to seek lawful treatment or to provide full information to their health care providers."¹⁵ HHS claims that new laws passed after *Dobbs* "**raised the prospect** that highly sensitive PHI would be disclosed"¹⁶ and that such laws "**could interfere** with individuals' longstanding expectations." It worries about what health care entities "**might be compelled**" to do.¹⁷ The Department's guesswork does not provide an adequate basis for the proposed rulemaking.

Having relied on reaction pieces and the Department's own conjectures, HHS somehow arrives at certain conclusions. The preamble claims that the Department has "determined . . . that information about reproductive health care . . . requires heightened protections."¹⁸ It claims that the *Dobbs* decision makes PHI related to "reproductive health care" "is now more acute than it was before."¹⁹ It states that because of *Dobbs* "effectuating the purposes of HIPAA now "require[s] regulatory provisions that restrict[] uses and disclosures of PHI related to [reproductive health care]."²⁰ But these bold, unsupported conclusions are not enough to meet HHS' legal obligation to justify new rulemaking. The Department's failure to justify the proposed rulemaking renders the Proposed Rule arbitrary and capricious under the Administrative Procedure Act.

II. The Proposed Rule makes the HIPAA Privacy Rule more, not less, confusing.

The Department's main argument throughout the preamble is that the Proposed Rule is needed to ameliorate alleged confusion about the HIPAA Privacy Rule in the wake of the *Dobbs* decision. HHS says *Dobbs* and subsequent legal developments have created "significant confusion for individuals, health care providers, family, friends, and caregivers regarding their ability to privately seek, obtain, provide, or facilitate health care."²¹ More specifically, HHS claims "regulated agencies" have expressed "confusion and concern as to the[ir] ability . . . to use or disclose PHI for" "criminal, civil, or administrative investigations into or proceedings about that health care."²² HHS claims that its Proposed Rule provides the "further clarification . . . needed to resolve this confusion and strengthen privacy protections."²³

¹³ 88 Fed. Reg. at 23519.

¹⁴ 88 Fed. Reg. at 23507 (emphasis added).

¹⁵ *Id.* (emphases added).

¹⁶ *Id.* at 23509 (emphasis added).

¹⁷ *Id.* at 23519 (emphasis added).

¹⁸ *Id.* at 23510.

¹⁹ *Id.* at 23510.

²⁰ 88 Fed. Reg. at 23519.

²¹ 88 Fed. Reg. 23509. *See also id.* at 23520 (claiming there is "ambiguity and confusion for individuals and health care providers . . . about when health information is protected under the HIPAA Rules"); *id.* at 23548 (alleging "significant confusion about the extent to which reproductive health care information is protected by the Privacy Rule").

²² 88 Fed. Reg. 23528.

²³ 88 Fed. Reg. 23509.

As shown above, the Proposed Rule does not demonstrate that there is a problem that needs to be solved. But even if it had, federal agencies must also “offer[] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”²⁴ An agency must “articulate a satisfactory explanation for its action,” including a “rational connection between the facts found and the choice made.”²⁵

Because this alleged “confusion” plays such a prominent role in HHS’ justification for its Proposed Rule, it is important to highlight the mind-numbing confusion that the Proposed Rule *would create*. This is most easily seen through the Proposed Rule’s additions to the Privacy Rule, which center on vague and undefined terms.

The byzantine complexity the Proposed Rule would create for covered entities stands in sharp contrast to the Department’s own requirement that state law enforcement actions justify their requests for PHI in “plain language.” The Proposed Rule’s attestation requirement (§ 164.509) states that a covered entity may not comply with a “subpoena, discovery request, or other lawful process” that requests “protected health information potentially related to reproductive health care” unless the request and justification is “written in plain language.” As the following examples show, the Proposed Rule fails the “plain language” test.

A. The Proposed Rule contains broadly defined and vague terms.

1. Public Health

The Department redefines “public health,” as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” to “population-level activities to prevent disease and promote health of populations.”²⁶ These activities, however, explicitly exclude “uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care” and “for the identification of any person in connection with a criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care.”²⁷ In short, the Proposed Rule has defined “reproductive health care” and abortion out of the definition of “public health.”²⁸ Not only is this definitional change arbitrary and capricious on simply a surface level reading of the text, but the administration has repeatedly included “reproductive health care” and abortion as part of “public health more broadly.”²⁹ This limitation inhibits state health departments’ collection of health data and investigations and enforcement of health and safety regulations.

2. Person

The Privacy Rule defines “person” as “natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.”³⁰ The Proposed Rule adds to

²⁴ *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 43 (1983).

²⁵ *Id.*

²⁶ 88 Fed. Reg. 23525.

²⁷ *Id.* at 23552.

²⁸ *Id.*

²⁹ Executive Order on Protecting Access to Reproductive Healthcare Services, <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/07/08/executive-order-on-protecting-access-to-reproductive-healthcare-services/>, Executive Order on Securing Access to Reproductive and Other Healthcare Services, <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/>.

³⁰ 88 Fed. Reg. 23523.

the definition of “person,” by specifying that a “natural person” means “a human being who is born alive.”³¹ According to the Proposed Rule, “natural person...does not include a fertilized egg, embryo, or fetus.”³² This addition to the previously held definition is not only inconsistent with Congressional intent and federal law, but it would also create confusion and tension for state laws that define “person” to include the unborn.

In 2019, HHS, under the Trump administration, enforced HIPAA against a Florida medical center for failing to provide a mother timely access to prenatal health records for her unborn child.³³ The Proposed Rule, in contrast, will directly exclude unborn children from HIPAA protections. The Resolution Agreement, in the 2019 case, by treating the unborn as any other human person under HIPAA, established a precedent of including the unborn in the law’s protections.³⁴ The Department is now bypassing this standard without regard to this previous action by the same Department. The Department’s justification for this redefinition of “person” is not only unsubstantiated by law but is also a reversal of the 2019 HHS enforcement of HIPAA. Rather than taking into consideration this 2019 case, the Department does not mention it and instead opts to create a new definition that is discriminatory by defining away the rights of the unborn.

The Department states that it is “clarifying the definition of “person” to reflect longstanding statutory language defining the term,” but the Department fails to cite any of this “longstanding language,” other than 1 U.S.C. § 8, and instead simply asserts that such “language” exists.³⁵ Moreover, 1 U.S.C. § 8 does not exclude the unborn from the definition of “person.”³⁶ To the contrary, that statute clearly states that “[n]othing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being ‘born alive’ as defined in this section.”³⁷ The Department also justifies its definition based on another law, the Social Security Act of 1935, that *does not specify* whether unborn human beings are included in the definition of “person” that “person” under HIPAA does not include the “unborn.”³⁸ If the Department was creating “consistent” language in federal law such a redefinition could be admirable, but instead the Department is misinterpreting or misrepresenting its cited authority.

Moreover, the Department ignores two other federal statutes that support a different definition of “person.” First, the *Genetic Information Nondiscrimination Act of 2008* not only includes explicit discussion of the “fetus” and “embryo” but also specifically protects the data of unborn persons.³⁹ Additionally, the *National Childhood Vaccine Injury Act* covers the unborn person independently for vaccine injuries due to maternal vaccination.⁴⁰ These two examples, among others, demonstrates that Congress does consider the interests of unborn human beings when it uses the term “person” in the health care context. The better reading of HIPAA is that the law looks out for the interests of the unborn, not exclude them.

³¹ *Id.* at 23552.

³² 88 Fed. Reg. at 23523.

³³ OCR Settles First Case in HIPAA Right of Access Initiative, Archived HHS Content, <https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2019/09/09/ocr-settles-first-case-hipaa-right-access-initiative.html>.

³⁴ Resolution Agreement, September 6, 2012, <https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/sites/default/files/bayfront-st-pete-ra-cap.pdf>.

³⁵ 88 Fed. Reg. at 23522.

³⁶ *Id.* at 23523.

³⁷ 1 U.S.C. §8(c).

³⁸ 88 Fed. Reg. at 23523.

³⁹ PUBLIC LAW 110–233, 122 Stat. 885.

⁴⁰ 42 USC 300aa-11.

Furthermore, since the Supreme Court decided *Dobbs* last summer, many states have passed or begun implanting laws that define “person” to include the unborn. One Wyoming law invokes the state’s constitution to define “person” to include “the life of an unborn baby.”⁴¹ Idaho law recognizes that a “fetus” or a “preborn child” is “an individual organism of the species *Homo sapiens* from fertilization until live birth.”⁴² South Dakota has de facto included the unborn as a person by signing a law that states an “[u]nauthorized abortion [is a] felony.”⁴³ The same law also states that “any person who intentionally kills a human fetus by causing an injury to its mother, which is not authorized by chapter 34-23A, is guilty of a Class 4 felony.”⁴⁴ Another South Dakota law also defines a “human being” as “an individual living member of the species of *Homo sapiens*, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation” and defines an “abortion” as “the intentional termination of the life of a human being in the uterus.”⁴⁵ Texas defines “unborn child” as an “individual living member of the homo sapiens species from fertilization until birth, including the entire embryonic and fetal stages of development.”⁴⁶ Finally, Arkansas defines the “unborn child” to mean “an individual organism of the species *Homo sapiens* from fertilization until live birth.”⁴⁷ These are just a few examples of the many state laws that recognize that an unborn child is a “person,” a “human being,” or a member of the species “*homo sapiens*.”⁴⁸

Not only is the Proposed Rule’s definition of “person” inconsistent with “longstanding” federal laws, but the Department’s definition also conflicts with the considered judgment of at least a third of the states. This Proposed Rule creates profound conflicts with state and federal laws. This contrived and politically motivated definition of “person” lacks Congressional intent. It is, therefore, arbitrary and capricious for the Department to subsume the responsibilities of Congress to define “person.” HHS should reject this unjustified and unscientific definition of “person” for purposes of the HIPAA Privacy Rule. This unjust and unjustified definition should likewise not be adopted by other agencies.

3. Reproductive Health Care

The Proposed Rule also offers broad definitions of “health care” and “reproductive health care.” First, the Department defines “health care” to include “supplies purchased over the counter or furnished to the individual by a person that does not meet the definition of a health care provider.”⁴⁹ Under the definition of “health care,” the Department adds in the Proposed Rule, “a subcategory” called “reproductive health care.”⁵⁰ The Proposed Rule’s definition of “reproductive health care” includes all “care, services, or supplies related to the reproductive health of the individual.”⁵¹

The Department admits that “reproductive health information is not easily defined or segregated.”⁵² Indeed, the Department’s proffered definition of “reproductive health care,” bolstered by

⁴¹ Wyoming; HB0152.

⁴² Idaho Code Ann. § 18-8801.

⁴³ S.D. Codified Laws § 22-17-5.1.

⁴⁴ *Id.*

⁴⁵ S.D. Codified Laws § 34-23A-1.

⁴⁶ Tex. Health & Safety Code Ann. § H-2-170.A.001.

⁴⁷ Ark. Code § 5-61-303.

⁴⁸ LA. REV. STAT. ANN. § 40:1061, Wis. Stat. Ann. § 940.04, Ky. Rev. Stat. Ann. § 311.772, Tenn. Code Ann. § 39-15-213, Miss. Code Ann. § 41-41-45, ALA. Admin. Code § 26-23H 1-8, and W. Va. Code Ann. § 16-2R-1, to 16-2R-7. Some of these state laws find their definition of person and the protection of the unborn from the point of conception in their state constitutions.

⁴⁹ 88 Fed. Reg. at 23527.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² 88 Fed. Reg. at 23521.

commentary and examples throughout the preamble, subsume a wide swath of activities that few would include under this category.

The Department's definition begins with § 160.103, which states that "reproductive health care includes all "care, services, or supplies related to the reproductive health of the individual." The Department asserts that this definition, like its definition of "health care," "applies broadly."⁵³ Though the Department's focus on Dobbs shows it is primarily focused on abortion, this definition of "reproductive health care" would not only cover surgical and chemical abortion, it would also cover contraception, emergency contraception, IVF treatments, pregnancy, miscarriage, fertility treatments, and sterilizing treatments.

The Proposed Rule also states that "reproductive health care" can be "related to reproductive organs, regardless of whether the health care is related to an individual's pregnancy or whether the individual is of reproductive age."⁵⁴ This is a clear indication that the Proposed Rule would also cover drugs and surgeries related to "gender transition," as puberty blockers, cross-sex hormones, and the removal of reproductive organs are all "health care related to reproductive organs." Pro "gender transition" advocacy groups are already celebrating that the Proposed Rule would cover not just "abortion and reproductive health care" but also "gender affirmation."⁵⁵

The Department also says that "reproductive health care" includes "supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health."⁵⁶ The decision to include non-prescription items as "health care" paves the way for future regulations that would allow non-health care providers to distribute abortion-inducing drugs and other drugs such as puberty blockers, which as shown below qualify under the Department's expansive definition of "reproductive health care." Lowering health care standards and encouraging "self-managed" abortions⁵⁷ puts the Department's progressive political agenda ahead of what should be the Department's focus: protecting the health of women and children.

4. Seeking, Obtaining, Providing, or Facilitating

As if its definition of "reproductive health care" was not broad enough on its own, the proposed additions to the Privacy Rule would also extend to the "seeking, obtaining, providing, or facilitating" of reproductive health care.⁵⁸ Section 164.502(a)(5)(iii)(B) defines "seeking, obtaining, providing, or facilitating" as including, but not limited to, any of the following:

expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

Put together, these provisions offer fifteen verbs to extend the reach of its protections for "reproductive health care"-related PHI. Each of these terms has a broad range of meanings, and it is beyond the scope of this public policy to explore them all. But perhaps one of the most problematic terms is "inducing," which means to "succeed in persuading or influencing (someone) to do something." As such, the Proposed Rule

⁵³ *Id.*

⁵⁴ 88 Fed. Reg. at 23527.

⁵⁵ Comment from American Academy of Family Physicians, HHS-OCR-2023-0006, HHS-OCR-2023-0006-0001, 2023-07517, <https://www.regulations.gov/comment/HHS-OCR-2023-0006-0062>.

⁵⁶ *Id.*

⁵⁷ 88 Fed. Reg. at 23519 and 21.

⁵⁸ § 164.502(a)(5)(iii)(A).

would prohibit covered entities from complying with subpoenas seeking information on whether someone was coerced into getting an abortion, which is a crime in most (if not all) states.

B. These critical terms are qualified by words and phrases that are not defined at all.

Unfortunately, it gets even worse. The Proposed Rule would not only force covered entities to wrestle with these poorly defined terms: the Proposed Rule also qualifies these terms with words and phrases that are themselves not defined and susceptible to a wide range of interpretations.

Under the Proposed Rule, covered entities would have to make judgment calls about the following issues:

- When is a “use[] and disclosures” of PHI “*for* [a] criminal, civil, or administrative investigation”? (§ 160.103)
- When is a “report of abuse, neglect, or domestic violence [] *based primarily on* the provision of reproductive health care”? (§ 164.512(c)(3))
- When is PHI “*potentially related to* reproductive health care”? (§164.509(a))
- When is a request for PHI “*in connection with* a criminal, civil, or administrative investigation”? (§ 160.103)
- When is a request for PHI “*in connection with* obtaining, providing, or facilitating reproductive health care”? (§ 160.103)
- When is a request for PHI “*in connection with* seeking, obtaining, providing, or facilitating reproductive health care”? (§ 164.502(a)(5)(iii)(A))
- When is a request for PHI “*in connection with* any person seeking, obtaining, providing, or facilitating reproductive health care” § 164.502(a)(5)(iii) (C)
- What is the legal difference between these *three nearly-identical phrases*?
- “in connection with obtaining, providing, or facilitating reproductive health care;”
- “in connection with *seeking*, obtaining, providing, or facilitating reproductive health care;” and
- “in connection with *any person seeking*, obtaining, providing, or facilitating reproductive health care.”
- When is a use or disclosure of PHI “*primarily* for the purpose of investigating or imposing liability on any person”? (§ 164.502(a)(5)(iii)(D))
- When is an investigation or legal action “*for the mere act* of seeking, obtaining, providing, or facilitating reproductive health care”? (§ 164.502(a)(5)(iii)(D))
- When is a use or disclosure of PHI “*primarily for* the purpose of investigating or imposing liability on any person”? (§ 164.502(a)(5)(iii)(D))

It would be impossible for a covered entity to understand its new obligations under this Proposed Rule without understanding these phrases: “*for*,” “*based primarily on*,” “*potentially related to*,” “*in connection with*,” “*mere act*” and “*primarily for*.” And yet, none the Proposed Rule defines any of these critical terms.

III. The Proposed Rule complicated covered entities’ decision-making process under the Privacy Rule.

The poorly defined terms and criteria described above are only part of the changes the Proposed Rule would introduce into the Privacy Rule. New substantive provisions, together with these new terms and criteria, create a new decision-tree for covered entities that is far more complicated and ill-defined than the process health care entities are accustomed to. The following is our effort to set out the questions

that covered entities would, under the Proposed Rule, have to ask and answer each time they are presented with a potential use or disclosure of PHI.

A. The Proposed Rule would make it harder for a covered entity to determine whether a proposed use or disclosure of PHI is permitted under the Privacy Rule.

HIPAA's Privacy Rule starts with the default rule that it is illegal for covered entities to use or disclose PHI except as permitted by § 164.502 or by 45 CFR Subpart C, which deals with HHS compliance and investigations.⁵⁹ Presently, a covered entity must determine if a potential use or disclosure falls under one of the categories set out in § 164.502(a)(1) or incorporated into that list by reference, especially § 164.512.

The Proposed Rule would make three important changes to § 164.512. First, the entire section is now subject to the new Reproductive Health Care Rule at § 164.502(a)(5)(iii), which is addressed separately below. Second, some *but not all* provisions in § 164.512 are subject to the new Attestation Requirement, § 164.509, which is also addressed below.

Third, the Proposed Rule would add a new Rule of Construction that *only* applies to § 164.512(c), which covers disclosures about *non-child* victims of abuse, neglect, or domestic violence. Though the first change to § 164.512 states that *all of* this section is now subject to the new Reproductive Health Care Rule, this third change says that nothing in § 164.512(c) permits disclosures prohibited by the Reproductive Health Care Rule “when the report . . . is based primarily on the provision of reproductive health care.” As noted above, these terms will cause confusion. But seemingly irreconcilable additions to § 164.512 will doubtless leave covered entities befuddled:

- If *all of* “the situations covered by” § 164.512 are now subject to the Reproductive Health Care Rule, what is the point of the Rule of Construction, which says that *some of* the situations covered § 164.512(c) are subject to the Reproductive Health Care Rule?
- How should a covered entity determine whether a “report of abuse, neglect, or domestic violence” is “based primarily on the provision of reproductive health care,” the standard set out in the Rule of Construction in § 164.512(c)?
- Given that the Proposed Rule defines “reproductive health care” to include “care . . . related to the reproductive health of the individual,”⁶⁰ and given that the definition of “care” includes “regard coming from desire or esteem,”⁶¹ is not *all* sexual abuse “based primarily on the provision of reproductive health care”?
- If a covered entity decides that a “report of abuse, neglect, or domestic violence” is *not* “based primarily on the provision of reproductive health care,” the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be “for a[n] investigation into . . . a person in connection with seeking, obtaining, providing, or facilitating reproductive health care,” the standard set out in § 164.502(a)(5)(iii)(A)(1)?⁶² If so, what is the difference between these two standards?

⁵⁹ 45 CFR § 164.502(a).

⁶⁰ § 160.103.

⁶¹ Care, Merriam-Webster, <https://www.merriam-webster.com/dictionary/care>.

⁶² The Surplusage Canon (*verba cum effectu sunt accipienda*) would seem to necessitate this possibility.

- If a covered entity decides that a “report of abuse, neglect, or domestic violence” is *not* “based primarily on the provision of reproductive health care,” the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be “for a[n] investigation into . . . a person in connection with seeking, obtaining, providing, or facilitating reproductive health care,” the standard set out in § 164.502(a)(5)(iii)(A)(1)?⁶³ If so, what is the difference between these two standards?
- If a covered entity decides that a “report of abuse, neglect, or domestic violence” is *not* “based primarily on the provision of reproductive health care,” the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be “primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care,” the standard set out in § 164.502(a)(5)(iii)(D)?⁶⁴ If so, what is the difference between these two standards?

Contrary to HHS’s representation, these proposed changes to the Privacy Rule would not give covered entities “further clarification”⁶⁵ on how to determine whether a proposed use or disclosure of PHI is permitted under 45 CFR § 164.512.

B. The proposed Attestation Requirement would make it more dangerous and complicated for law enforcement to request PHI, and more dangerous and complicated for covered entities to respond to such requests.

The proposed Attestation Requirement, §264.509, likewise will make it more complicated for law enforcement entities to pursue and for covered entities to cooperate with critical public health priorities related to sexual crimes. Law enforcement would have to balance important interests related to keeping activities confidential with new obligations to explain themselves to covered entities. Covered entities will have to make difficult assessments about whether proffered attestations meet the vague standards of the proposed Reproductive Health Care Rule. Covered entities will also have to weigh the risks of being held in contempt of court for refusing a valid subpoena against the risks of HHS bringing an enforcement action for complying with the valid subpoena.

Suppose a prosecutor presents a hospital with a subpoena seeking PHI related to an alleged crime. Presuming that the subpoena is clearly for a judicial and administrative proceeding (§ 164.512(e)) or for law-enforcement purposes (§ 164.512(f)), the hospital will have to determine whether the PHI sought is “potentially related to reproductive health care.” If the hospital thinks the PHI sought qualifies—or, more to the point if the covered entity is afraid that HHS might declare that the PHI qualifies—the hospital will have to refuse to comply with the court order unless the prosecutor supplies an attestation. If the prosecutor refuses to do so—because she determines that the subpoena does not seek information “potentially related to reproductive health care,” or else because she finds the attestation requirement unlawful or unnecessary for other reasons—the hospital will have to choose between defying a court order and risking a HIPAA violation.

If the prosecutor agrees to provide an attestation, the prosecutor will then have to determine what constitutes a “valid” attestation, a task that begins with attempting to interpret the Reproductive Health Care Rule. Because that Rule is so complicated and ill-defined, it is difficult to understand how a

⁶³ *Ibid.*

⁶⁴ *Ibid.*

⁶⁵ 88 Fed. Reg. at 23509.

prosecutor could explain why she believed she had complied with the Reproductive Health Care Rule while still adhering to the Attestation Requirement's "plain language" requirement.

Once the attestation is provided, the pressure is then on the hospital to determine whether the attestation is "valid." If not, it would be illegal for the hospital to comply. To determine validity, the hospital must ask and answer the following questions:

- Does the attestation verify that the use or disclosure of PHI is not "otherwise" prohibited by the Reproductive Health Care Rule? (§164.509(b)(1)(ii))
- Does the attestation separately include a "clear statement that the use or disclosure is not for a purpose prohibited under" the Reproductive Health Care Rule? (§164.509(c)(1)(iv))
- Does the attestation identify the information requested in a specific fashion? (§164.509(c)(1)(ii))
- Does the attestation identify the name of the person whose PHI is sought? (§164.509(c)(1)(i)(A))
 - If not, would it have been "practicable" for the attestation to do so? (§164.509(c)(1)(i)(A))
 - If it was "not practicable" for the attestation to do so, does the attestation include "a description of the class of individuals whose [PHI] is sought"? (§164.509(c)(1)(i)(B))
- Does the attestation include the "name" of the "person(s)" "or class of persons" "who are requested to make the use or disclosure"? (§164.509(c)(1)(ii))
 - If not, does it include "other specific information" regarding the person or persons "who are requested to make the use or disclosure"? (§164.509(c)(1)(ii))
- Does the attestation include the "name" of the "person(s)" "or class of persons" "to whom the covered entity is to make the requested use or disclosure"? (§164.509(c)(1)(iii))
 - If not, does it include "other specific information" regarding the person or persons "to whom the covered entity is to make the requested use or disclosure"? (§164.509(c)(1)(iii))
- Is the attestation signed by the person requesting the PHI? (§164.509(c)(1)(v))
 - If not, is it signed by a representative of the person requesting the information? (§164.509(c)(1)(v))
 - If it is signed by a representative, does the attestation also include a "description of such representative's authority to act for the person"? (§164.509(c)(1)(v))

If the covered entity answers no to *any* of these questions, it *must reject* the attestation and ask the prosecutor to try again. If the prosecutor refuses, the hospital must again choose between defying a court order and defying HHS.

But even if the hospital deems the attestation valid so far, it must still continue to make a number of more nuanced and complicated judgments about the attestation.

- Does the attestation contain any "element or statement" that is "not required by [§ 164.509(c)]"? (§ 164.509(b)(2)(ii))
 - If so, the attestation is invalid, and it would be illegal for the hospital to comply.

Note that while § 164.509(b)(1)(ii) renders an attestation invalid if it contains any “element or statement” that is “not required by [§ 164.509(c)],” not every element that must be included in a valid attestation is found in § 164.509(c). For example, § 164.509(b)(1)(ii) states that a valid attestation must verify that “the use or disclosure is not otherwise prohibited by” the Reproductive Health Care Rule. ***As such, it seems impossible for a covered entity to determine that an attestation complies with both § 164.509(b)(1)(ii) and 164.509(b)(2)(ii). If this reading is correct, then the Proposed Rule would make it illegal under HIPAA for a covered entity to ever comply with a subpoena that requests “protected health information potentially related to reproductive health care.”***

Is the attestation “combined with any other document”? (§ 164.509(b)(3))

- If so, the attestation is invalid, and it would be illegal for the hospital to comply.
- Does the covered entity have “actual knowledge that material information in the attestation is false”? (§ 164.509(b)(2)(iv))
 - If so, the attestation is invalid, and it would be illegal for the hospital to comply.

It is unclear from the Proposed Rule what sort of due diligence a hospital must undertake to determine whether the corporation has “actual knowledge” of this nature?

- Is the attestation “written in plain language”? (§ 164.509(c)(2))
 - If not, the attestation is invalid, and it would be illegal for the hospital to comply.

Given the complexity of the proposed Attestation Rule and given the prolix manner in which the proposed § 164.509 is written, it is difficult to imagine that a document could answer all of these complicated and poorly-worded questions and still be written in plain language.

Again, if the covered entity determines that the attestation is deficient by any of these measures, it must reject the attestation and ask the prosecutor to try again. If the prosecutor refuses, the hospital must again choose between defying a court order and defying HHS.

But even now, the covered entity is still not in the clear. Section 164.509 also creates ongoing obligations that adhere “during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation.” The hospital must continue to ask itself the following questions:

- Has the covered entity “discover[ed] information reasonably showing that representations in the attestation were materially false”? (§ 164.509(d))

Note that this is a *lower bar* than what § 164.509 requires for a covered entity’s *initial* determination that an attestation is valid. Under § 164.509(2)(iv), a covered entity would have to have “actual knowledge” that “material information in the attestation is false.” Otherwise, the attestation is valid. But once the covered entity determines that an attestation is valid and starts complying with a subpoena, § 164.509(d) states that the entity “must cease” if it has: (1) “information reasonably showing” (a lower threshold than the “actual knowledge” standard in § 164.509(2)(iv)) that (2) *any* representation in the attestation (a lower threshold than the “material information in the attestation” standard in § 164.509(2)(iv)) is false.

Yet, in another regard, § 164.509(d) sets a *higher bar* than § 164.509. A covered entity must initially determine whether a representation is “false,” but later must judge whether a representation is “materially false.”⁶⁶

- If the covered entity has discovered “information” that is “materially false,” is that information “leading to uses or disclosures for a prohibited purpose”? (§ 164.509(d))
 - If the covered entity says *yes to both* questions, “the covered entity must cease such use or disclosure.” (§ 164.509(d)) An affirmative answer to one or the other would not appear to authorize a covered entity to ignore a subpoena.

These differing standards create a dizzying array of complicated scenarios for covered entities to navigate. For example, what is a covered entity to do if, while it is evaluating an attestation, it determines it does not have “actual knowledge” that “material information” in the attestation is “false,” but it does have “information reasonably showing” that a non-material representation in the attestation is “materially false”? It would appear that the hospital would be in contempt of court if it refused to accept the attestation, but then would be violating HIPAA if it complied with the subpoena. How does HHS expect covered entities to proceed in such situations?

C. Even if a proposed use or disclosure is permitted under § 164.502 and satisfies the Attestation Rule (if applicable), a covered entity must still judge the proposed use or disclosure under the new Reproductive Health Care Rule.

We now come to the most important and complex part of the Proposed Rule, the Reproductive Health Care Rule, located in § 164.502(a)(5)(iii). The Proposed Rule makes clear in several places that this provision is a super regulation that would override all other aspects of the HIPAA Privacy Rule that might authorize the release of PHI. For example, the Proposed Rule would add new language to the front of § 164.512 to clarify that uses permitted there are still prohibited when they conflict with the new Reproductive Health Care Rule. The Reproductive Health Care Rule also makes this unmistakably clear: “a covered entity or business may not use or disclose protected health information” when § 164.502(a)(5)(iii) applies. It is, therefore, crucial that covered entities are able to comprehend what this proposed Rule entails and what it demands of them.

1. Is the proposed disclosure “for a criminal, civil, or administrative investigation into or a proceeding against any person”?

The Reproductive Health Care Rule has several parts, and there is no obvious way for a covered entity to navigate its requirements. But it may be simplest, to begin with the general prohibition found in § 164.502(a)(5)(iii)(A). This provision may itself be divided into two inquiries. First, a covered entity must determine whether a proposed use or disclosure of PHI is “for a criminal, civil, or administrative investigation into or proceeding against any person.”⁶⁷ This inquiry is also satisfied if the covered entity discerns that the proposed use or disclosure is “for the purpose of initiating” such an investigation or proceeding.⁶⁸ If no, the Reproductive Health Care Rule does not apply. But if the covered entity finds this is the case, it must proceed to the next inquiry.

⁶⁶ To determine whether a statement is “false,” one must simply uncover whether it was untrue when made. But to judge a statement “materially false,” one must additionally conclude that the statements “has a natural tendency to influence, or [is] capable of influencing, the decision of the decision making body to which it was addressed.” *Neder v. United States*, 527 U.S. 1, 16 (1999).

⁶⁷ § 164.502(a)(5)(iii)(A)(1).

⁶⁸ § 164.502(a)(5)(iii)(A)(2).

To understand the confusion the Proposed Rule will create, consider how it applies to a health care professional's legal duty as a mandatory reporter of child abuse and neglect. HHS states that the Proposed Rule "permits a regulated entity to use or disclose PHI to report known or suspected child abuse or neglect if the report is made to a public health authority that is authorized by law to receive such reports."⁶⁹ It claims that the Proposed Rule would not "disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities."⁷⁰ But the Department's reassurances cannot alter the plain meaning of the proposed regulatory text.

When a health care professional determines that she has a reasonable basis to conclude that a child has been sexually abused, the report she makes to the designated public official is made "for the purpose of initiating" "a criminal, civil, or administrative investigation into or proceeding against [a] person." The preamble reassures covered entities that their health care professionals may continue to fulfill their duties as mandatory reporters, but the proposed regulatory text appears to state otherwise.

2. Would the anticipated investigation or proceeding be "in connection with seeking, obtaining, providing, or facilitating reproductive health care?"

The second inquiry under § 164.502(a)(5)(iii)(A) requires a covered entity to determine whether the investigation or proceeding in question would be "in connection with seeking obtaining, providing, or facilitating reproductive health care." As explained above, there are three parts to this standard. The Proposed Rule offers expansive and non-exhaustive definitions of "reproductive health care" and "seeking, obtaining, providing, or facilitating." The third part of this quote, "in connection with," is not defined at all. And the preamble asserts that these phrases, individually and collectively, cover a huge swath of human activity.

The Proposed Rule would put covered entities to the daunting task of having to decide when these criteria are triggered. Some of the difficult questions covered entities will have to ask themselves would include the following:

- Would the anticipated investigation or proceeding involve, at some level, what the Proposed Rule defines as "reproductive health care"?
- If so, would the anticipated investigation or proceeding be about someone "seeking, obtaining, providing, or facilitating" reproductive health care?
- If not, would the anticipated investigation or proceeding be "in connection with" someone seeking, providing, or facilitating" reproductive health care?

⁶⁹ 88 Fed. Reg. at 23526. The Proposed Rule's allowances for child abuse reporting are much more limited than it first appears. First, HHS states that this permission is limited "to the minimum necessary to make the report." 88 Fed. Reg. at 23526. It is unclear what standards the Department will use in deciding whether a reporter has crossed this "minimum necessary" threshold. Second, this permission "does not include permission for the covered entity to respond to a request for PHI for a criminal, civil, or administrative investigation into or proceeding against a person based on suspected child abuse." *Id.* "Any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity (other than to clarify the PHI provided in the report) or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity would be required to meet the conditions of disclosures to law enforcement or for other investigations or legal proceedings." *Id.*

⁷⁰ 88 Fed. Reg. at 23527.

If the covered entity determines that the proposed use or disclosure would not be related to a government action “in connection with” any of the wide range of activities indicated above, the Reproductive Health Care Rule would not apply. Otherwise, the covered entity must continue on to the next inquiry.

Consider again how this part of the Reproductive Health Care Rule would apply to a health care professional’s legal duty as a mandatory reporter of child abuse and neglect. As described above, a report about suspected child abuse is made “for the purpose of investigating or imposing liability on” the suspected abuser. Now the covered entity must decide whether the anticipated investigation the mandatory report will trigger would be “in connection with seeking, obtaining, providing, or facilitating reproductive health care.” Given the broad and unbounded definition in the Proposed Rule, a covered entity could reasonably conclude (or fear) that a report about suspected child sexual abuse or a report about a suspected coerced abortion would qualify.

3. Was the reproductive health care activity in question “lawful” where it was sought, obtained, provided, or facilitated?

The Rule of Applicability in § 164.502(a)(5)(iii)(C) requires the covered entity to determine whether the reproductive health care activity in question was legal where it was sought, obtained, provided, or facilitated. The Rule of Applicability provides three scenarios to illustrate its application, covering multistate investigations, single-state investigations, and investigations into “care” protected by (HHS’s interpretation of) federal law.

The Department states that the Rule of Applicability “would limit the new prohibition to certain categories of instances in which the state lacks any substantial interest in seeking the disclosure.”⁷¹ But it is far from clear that the Department has achieved this goal by making it illegal for a covered entity to use or disclose PHI “in connection with” “reproductive health care” that is “lawful.”

As noted already, there are a myriad of complexities and ambiguities within the proposed Reproductive Health Care Rule. But the Rule of Applicability now adds another with the term “lawful.” This term is not defined, so covered entities would have to look to the preamble for clues as to how this term will be interpreted and enforced.

The first difficulty is attempting to discern whether “lawful” applies to a drug or procedure in general or under particular circumstances. The preamble does not clearly say one way or the other. In some places, HHS seems to be focused on whether a procedure (such as an abortion) is categorically prohibited, at least under certain circumstances (for example, whether the medical professional has a good-faith belief that the unborn human being is at more than twelve weeks gestation).

In other places, the Department seems to anticipate a more granular inquiry. For example, HHS states that the Proposed Rule would address situations where law enforcement seeks PHI to determine whether or not a prescription is used “for purposes that are permissible under state law.”⁷² This would require a covered entity to make a judgment about the intentions of the relevant law enforcement officer or agency, the intentions of the person seeking the prescription, the intentions of the health care professional, or perhaps all of the above.

These are complicated, subjective determinations requiring expertise and judgment calls that are more in the purview of lawyers than health care professionals. Covered entities will also have to consider their potentially conflicting legal obligations under state law and federal regulations.

⁷¹ 88 Fed. Reg. at 23522.

⁷² 88 Fed. Reg. at 23520.

If the covered entity determines that any of the reproductive health care activities in question were not legal, the Reproductive Health Care Rule does not apply. But if the activities in question were legal, the covered entity must then move on to the Reproductive Health Care Rule's Rule of Construction.

4. Would the proposed use or disclosure be “primarily” for the purpose of investigating or imposing liability on any person for “the mere act” of seeking, obtaining, providing, or facilitating reproductive health care”?

The final part of the Reproductive Health Care Rule is the Rule of Construction (§ 164.502(a)(5)(iii)(D)). This inquiry attempts to narrow the Reproductive Health Care Rule by introducing two new terms: “primarily” and “mere act.”

Unfortunately, the Proposed Rule does not define either “primarily” or “mere act,” and it does not provide examples that would be sufficient to help covered entities understand what they are supposed to do or how they are supposed to apply these new phrases.

If the covered entity finds that the proposed use would not be “primarily for the purpose of investigating or imposing liability” for a “mere act” related to reproductive health care, the Reproductive Health Care Rule does not apply. But if the covered entity answers this question in the affirmative, the Reproductive Health Care Rule prohibits any disclosure that is otherwise permitted under the HIPAA Privacy Rule.

IV. In light of the above, the Proposed Rule would likely intimidate covered entities into refusing to comply with longstanding professional and legal obligations to use or disclose PHI.

The Department has failed to show that the Supreme Court's *Dobbs* decision has created “confusion” that justifies the Proposed Rule. But whatever confusion there might be about how *Dobbs* and related legal developments have changed covered entities' obligations under HIPAA, the Proposed Rule would make things much worse by introducing new counter-intuitive and difficult terms, by qualifying these terms in ways that make them almost impossible to understand and apply, and by adding considerable complexity to the decision-making process health covered entities must undergo before complying with court orders.

In this final section, we offer three additional reasons why we are concerned that the Proposed Rule would have the practical effect of intimidating covered entities into refusing to comply with their longstanding professional and legal obligations to use or disclose PHI. Given the administration's aggressive position on abortion and other hotly-debated issues related to “reproductive health care;” given the administration's broad authority to develop, interpret, enforce, and adjudicate matters related to the HIPAA Privacy Rule; and given the serious criminal, civil, and professional consequences that can follow from an HHS determination that the Privacy Rule has been violated, the public should be seriously concerned that the Proposed Rule will chill covered entities from complying with their moral and legal obligations to help protect vulnerable children and adults.

A. Health care professionals would be aware that the administration rejects *Dobbs* and has been a zealous advocate for radical procedures.

First, health care professionals would have to take into account that this Proposed Rule has been developed by an administration and under the authority of an HHS Secretary that have been outspoken about their opposition to *Dobbs* and that have a history of taking aggressive legal positions in the service of their pro-abortion and pro-gender-transition agendas.

The Proposed Rule makes the Department’s hostility and intention plain. For example, it states that the Proposed Rule is designed to frustrate state efforts to seek PHI for what it calls “punitive non-health purposes.”⁷³ The Proposed Rule also seeks to thwart law enforcement efforts to “request PHI from regulated entities for use against individuals.”⁷⁴ To explain what sorts of uses it has in mind, HHS cites a report from a “reproductive justice” group that laments that states are using reports from “designated mandatory reporters” and “police recovery of fetal remains” to enforce laws against second and third trimester “self-managed” chemical abortions.⁷⁵

However, as the Supreme Court affirmed in *Dobbs*, states have legitimate interests in protecting unborn human life and preventing the pain that unborn humans experience in abortions. The administration also issued statements in the wake of *Dobbs* that make its positions and its policy objectives clear.⁷⁶

The administration is, of course, entitled to advocate for its policy objectives, but it is inappropriate for the Department to use the Privacy Rule to undermine states’ rights, especially as Congress has not asserted a compelling interest in protecting access to abortion.

B. The administration’s policy preferences are especially relevant given that HHS performs legislative, executive, and judicial functions related to the Privacy Rule.

The administration’s policy preferences would not be so critical were the Proposed Rule not so vague and complicated, and if HHS did not have such an incredible and unchecked range of powers related to its development and implantation. As noted in the Proposed Rule, the HHS Secretary has granted the Office of Civil Rights (“OCR”) authority to “make decisions regarding the[] implementation, interpretation, and enforcement” of the HIPAA Privacy Rule.⁷⁷

The following chart, developed by HHS’s OCR, demonstrates the Department’s and more broadly the executive branch’s authority related to the HIPAA Privacy Rule:⁷⁸

⁷³ 88 Fed. Reg. at 23516.

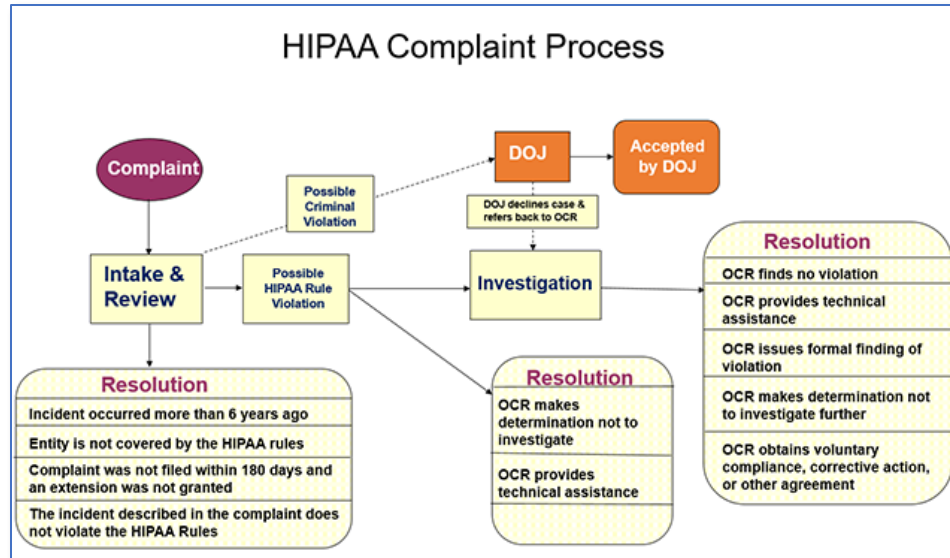
⁷⁴ 88 Fed. Reg. at 23519.

⁷⁵ Laura Huss, Farah Diaz-Tello, Colleen Samari, “Self-Care, Criminalized: August 2022 Preliminary Findings,” at 2-3, <https://www.ifwhenhow.org/resources/self-care-criminalized-preliminary-findings/> (cited at 88 Fed. Reg. at 23520 n.178).

⁷⁶ See Rachel Morrison, The Biden Administration’s Post-*Dobbs*, Post-*Roe* Response, Federalist Society, July 13, 2022, <https://fedsoc.org/commentary/fedsoc-blog/the-biden-administration-s-post-dobbs-post-roe-response>.

⁷⁷ 88 Fed. Reg. at 23514 (citing various executive actions).

⁷⁸ Enforcement Process, <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/enforcement-process/index.html>.



C. The legal and professional consequences of a HIPAA violation would color how health care professionals interpret and apply the Proposed Rule.

Finally, covered entities and health care professionals would be interpreting the Proposed Rule in light of the considerable consequences that can come from a determination that the HIPAA Privacy Rule has been violated. There are “severe penalties for violations, including prison sentences of up to 10 years and monetary fines of up to \$250,000.”⁷⁹ Additionally, health care professionals can suffer profound professional consequences if they are deemed to have participated in a violation of the HIPAA Privacy Rule.⁸⁰

CONCLUSION

We urge the Departments to abandon and withdraw the Proposed Rule.

⁷⁹ 88 Fed. Reg. at 23511 (citing 42 U.S.C. § 1320d-6(b)).

⁸⁰ See, e.g., HHS Office for Civil Rights Reaches Agreement with Health Care Provider in New Jersey That Disclosed Patient Information in Response to Negative Online Reviews, <https://www.hhs.gov/about/news/2023/06/05/hhs-office-civil-rights-reaches-agreement-health-care-provider-new-jersey-disclosed-phi-response-negative-online-reviews.html>; HHS Office for Civil Rights Settles HIPAA Investigation with Arkansas Business Associate MedEvolve Following Unlawful Disclosure of Protected Health Information on an Unsecured Server for \$350,000, <https://www.hhs.gov/about/news/2023/05/16/hhs-office-civil-rights-settles-hipaa-investigation-arkansas-business-associate-medevolve-following-unlawful-disclosure-phi-unsecured-server-350-000.html>; OCR Settles Three Cases with Dental Practices for Patient Right of Access under HIPAA, <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/september-2022-right-of-access-initiative/index.html>.

Sincerely,

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