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**EO 12866 Meeting
“Proposed Modifications to the HIPAA Privacy Rule
to Support Reproductive Health Care Privacy”
RIN 0945-AA20**

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Thank you for the opportunity¹ to provide comments on OIRA’s review of HHS’s proposed rule, “HIPAA Privacy Rule To Support Reproductive Health Care Privacy,” 88 Fed. Reg. 23506 (April 17, 2023). I, Eric Kniffin, am a former attorney in the DOJ Civil Rights Division under Presidents George W. Bush and Obama. I also have also been involved in extensive civil rights litigation against HHS as counsel for the Becket Fund for Religious Liberty and in private practice, including successful lawsuits against HHS’s contraception mandate and HHS’s original Section 1557 transgender mandate. Attending with me is my Natalie Dodson. Both of us serve as scholars in the HHS Accountability Project (Project) at the Ethics and Public Policy Center (EPPC).

For the reasons set out below, and as set out in more detail in our public comment to HHS,² the proposed rulemaking is contrary to law. 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*. It would create *more confusion* by greatly complicating the decision-making process a covered entity must undergo when deciding whether to use or disclose PHI. The Proposed Rule would introduce new counter-intuitive and difficult terms. It also would qualify these terms in ways that make them almost impossible to understand and apply. It would also add considerable complexity to the decision-making process health covered entities must undergo before complying with court orders.

But the Proposed Rule does not merely make the Privacy Rule more confusing and complicated. Covered entities would have to navigate this confusion knowing that HHS—the

¹ As OMB cancelled a previous EO 12866 meeting it scheduled with EPPC on another rule, we are glad you are willing to hear EPPC scholars’ input on this rule. See Rachel N. Morrison, *Biden and Becerra Kill Democratic Norms in Rush to Fund Big Abortion*, National Review, Oct. 8, 2021, <https://www.nationalreview.com/bench-memos/biden-and-becerra-kill-democratic-norms-in-rush-to-fund-big-abortion/>.

² <https://eppc.org/wp-content/uploads/2023/07/EPPC-Scholars-Comment-Opposing-the-HIPAA-Privacy-Reproductive-Health-Care-NPRM.pdf>.

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 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 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.

All of these problems give rise to profound federalism and economic concerns that are not adequately addressed in the proposed rule.

Perhaps the best and easiest way to capture the havoc that this proposed rule would create is to put oneself in the shoes of a general counsel for a covered entity. You are comfortable with current HIPAA regulations and have developed and overseen policies and procedures on how the entity and its medical professionals will meet its obligations under HIPAA’s Privacy Rule.

Now imagine the proposed rule is finalized. Does this new set of Privacy Rule regulations make your job easier or harder? Is your decision tree for complying with the Privacy Rule get more or less complicated? Have your difficult judgment calls gotten fewer or have the multiplied? Are you going to have fewer or more conflicts between subpoenas and court orders and with what you believe (or fear) HHS’s Privacy Rule regulations require?

For all the reasons set out below, we submit that the answers to these questions are obvious. If a request for PHI comes anywhere close to seeking information about abortion or “gender transition”—two of this administration’s most important policy interests—these proposed rules are a nightmare for covered entities.

Unfortunately, we suspect that this is exactly the point. This administration wants almost limitless access to abortions and “gender transitions.” But Congress and state legislatures have been loud and clear that they don’t share this administration’s zeal. So, as though of us in the HHS Accountability Project have seen time and time again, this administration turns to the regulatory process to try to give its constituents “wins” that it cannot get through the legislative process. That makes this proposed rule a profound and glaring abuse of the regulatory process.

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

1. There is no need for federal regulatory action.

- ***Purported need.*** For all rulemaking, agencies must identify a need and demonstrate how the rule meets that need. Federal administrative agencies are required to engage in “reasoned decision making.”³ To justify replacing current regulations, an agency must

³ *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015).

provide specific evidence as to how the current regulations are causing harm or burdens and how the Proposed Rule would remedy the alleged defects *without* causing equal or greater harms and burdens.⁴

- 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.
- ***Alleged Confusion.*** HHS’s justification for creating new rulemaking 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. HHS repeatedly asserts—but never demonstrates—that *Dobbs* has created “significant confusion about the extent to which reproductive health care information is protected by the Privacy Rule.”⁶
- Though the Proposed Rule was issued less than ten months after the *Dobbs* decision, HHS claims that it had already “carefully analyzed” the issue.⁷ However, the Proposed Rule’s preamble does not demonstrate any actual problem that needs to be solved.
 - ***Short-term reactions and unsupported claims do not justify rulemaking.*** 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*,⁸ a JAMA Network article published *seven days* later,⁹ a New Yorker piece published *eight days* after *Dobbs* decision,¹⁰ and a blog post from the Federal Trade Commission released *twenty-one days* after *Dobbs*.¹¹ HHS relies on *at least eleven other reports* published in the summer of 2022.¹²
 - ***That HIPAA allows law enforcement to investigate crimes does not justify rulemaking.*** The Department also relies on a “recently filed complaint” where a plaintiff alleges that her health-care provider falsified medical records because of *Dobbs*.¹³ 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 individuals and health care providers in potential civil or

⁴ *Id.* 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 23548.

⁷ *Id.* at 23510.

⁸ *Id.* at 23519 n.162.

⁹ *Id.*

¹⁰ *Id.* at 23509 n.25.

¹¹ *Id.* at 23510 n.28.

¹² *See*, for example, 88 Fed. Reg. at 23519 nn. 163, 166, and 169, *id.* at 23520 nn. 171 and 174.

¹³ 88 Fed. Reg. at 23519 and n.180.

criminal jeopardy when PHI related to an individual's reproductive health is used and disclosed.”¹⁴ Nonetheless, it is difficult to understand how these alleged crimes justify the Proposed Rule.

- **HHS's conjectures do not justify rulemaking.** 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.”¹⁵ 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.”¹⁶ HHS claims that new laws passed after *Dobbs* “**raised the prospect** that highly sensitive PHI would be disclosed”¹⁷ and that such laws “**could interfere** with individuals’ longstanding expectations.” It worries about what health care entities “**might be compelled**” to do.¹⁸ 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.”¹⁹ It claims that the *Dobbs* decision makes PHI related to “reproductive health care” “is now more acute than it was before.”²⁰ It states that because of *Dobbs* “effectuating the purposes of HIPPA now “require[s] regulatory provisions that restrict[] uses and disclosures of PHI related to [reproductive health care].”²¹ 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.

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

- As noted, the Department’s justification for new rulemaking rests entirely on its claim that *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.”²² More specifically, HHS

¹⁴ *Id.* at 23519.

¹⁵ *Id.* at 23507 (emphasis added).

¹⁶ *Id.* (emphases added).

¹⁷ *Id.* at 23509 (emphasis added).

¹⁸ *Id.* (emphasis added).

¹⁹ *Id.* at 23510.

²⁰ *Id.*

²¹ *Id.* at 23519.

²² *Id.* at 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

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.”²³ HHS claims that its Proposed Rule provides the “further clarification . . . needed to resolve this confusion and strengthen privacy protections.”²⁴

- 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.”²⁵ An agency must “articulate a satisfactory explanation for its action,” including a “rational connection between the facts found and the choice made.”²⁶
- 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*.
- In other words, even if *Dobbs* created some confusion about the HIPAA privacy rule, *HHS’s byzantine proposal would make things exponentially worse*.
- This is most easily seen through the Proposed Rule’s additions to the Privacy Rule, which center on vague and undefined terms.
- One way to measure the failure of the proposed rule is to compare it to the proposal’s own “plain language” requirement in the new attestation requirement. Proposed section 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.

(i) Public Health

- The Proposed Rule has defined “reproductive health care” and abortion out of the definition of “public health.”²⁷ Not only is this definitional change arbitrary and capricious on simply a surface level reading of the text, but the administration has

“significant confusion about the extent to which reproductive health care information is protected by the Privacy Rule”).

²³ *Id.* at 23528.

²⁴ *Id.* at 23509.

²⁵ *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 43 (1983).

²⁶ *Id.*

²⁷ *Id.*

repeatedly included “reproductive health care” and abortion as part of “public health more broadly.”²⁸

- This new definition is counterintuitive and appears to be driven by the administration’s political goal of inhibiting state health departments’ collection of health data and investigations and enforcement of health and safety regulations. That is not a lawful use of HHS’s delegated authority under HIPAA.

(ii) Person

- The Privacy Rule defines “person” as “natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.”²⁹ The Proposed Rule adds to the definition of “person,” by specifying that a “natural person” means “a human being who is born alive.”³⁰ According to the Proposed Rule, “natural person...does not include a fertilized egg, embryo, or fetus.”³¹ 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.³² 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.³³ 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

²⁸ 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/>.

²⁹ 88 Fed. Reg. 23523.

³⁰ *Id.* at 23552.

³¹ *Id.* at 23523.

³² 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>.

³³ 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>.

such “language” exists.³⁴ Moreover, 1 U.S.C. § 8 does not exclude the unborn from the definition of “person.”³⁵ 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.”³⁶ 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.”³⁷ 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.³⁸ Additionally, the *National Childhood Vaccine Injury Act* covers the unborn person independently for vaccine injuries due to maternal vaccination.³⁹ These two examples, among others, demonstrate 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.
- Furthermore, since the Supreme Court decided *Dobbs* last summer, many states have passed or begun implementing 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.”⁴⁰ Idaho law recognizes that a “fetus” or a “preborn child” is “an individual organism of the species Homo sapiens from fertilization until live birth.”⁴¹ South Dakota has de facto included the unborn as a person by signing a law that states an “[u]nauthorized abortion [is a] felony.”⁴² 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.”⁴³ 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.”⁴⁴ Texas defines “unborn child” as

³⁴ 88 Fed. Reg. at 23522.

³⁵ *Id.* at 23523.

³⁶ 1 U.S.C. §8(c).

³⁷ 88 Fed. Reg. at 23523.

³⁸ Pub. L. 110–233, 122 Stat. 885.

³⁹ 42 U.S.C. 300aa-11.

⁴⁰ Wyoming; HB0152.

⁴¹ Idaho Code Ann. § 18-8801.

⁴² S.D. Codified Laws § 22-17-5.1.

⁴³ *Id.*

⁴⁴ S.D. Codified Laws § 34-23A-1.

an “individual living member of the homo sapiens species from fertilization until birth, including the entire embryonic and fetal stages of development.”⁴⁵ Finally, Arkansas defines the “unborn child” to mean “an individual organism of the species Homo sapiens from fertilization until live birth.”⁴⁶ 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.”⁴⁷

- In short, 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.

(iii) 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.”⁴⁸ Under the definition of “health care,” the Department adds in the Proposed Rule, “a subcategory” called “reproductive health care.”⁴⁹ The Proposed Rule’s definition of “reproductive health care” includes all “care, services, or supplies related to the reproductive health of the individual.”⁵⁰
- The Department admits that “reproductive health information is not easily defined or segregated.”⁵¹ Indeed, the Department’s proffered definition of “reproductive health care,” bolstered by 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.”⁵² 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

⁴⁵ Tex. Health & Safety Code Ann. § H-2-170.A.001.

⁴⁶ Ark. Code § 5-61-303.

⁴⁷ 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.

⁴⁸ 88 Fed. Reg. at 23527.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 23521.

⁵² *Id.*

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.”⁵³ 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.”⁵⁴
- Every day it becomes more clear that this administration’s and this HHS leadership’s unblinking acceptance of gender ideology is unscientific and harmful. It is critical that the federal government and states be free to and actually collect data on “gender transition” interventions for minors so the public can better understand how many minors are being subjected to these life-altering experiments, under what conditions, and with what results. HHS’s proposed rule would frustrate this critical inquiry to protect its ideological commitment from scrutiny. That is an abuse of power and contrary to law.
- 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.”⁵⁵ 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” abortions⁵⁶ puts the Department’s progressive political agenda ahead of what should be the Department’s focus: protecting the health of women and children.

(iv) 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.⁵⁷ 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

⁵³ *Id.* at 23527.

⁵⁴ 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>.

⁵⁵ *Id.*

⁵⁶ 88 Fed. Reg. at 23519 and 21.

⁵⁷ 45 C.F.R. 164.502(a)(5)(iii)(A).

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 comment 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 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.

3. 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.
- Here is a helpful exercise: suppose you are a general counsel at a covered entity. Right now, HIPAA privacy rule questions are pretty simple. In most circumstances, the decision tree goes like this:
 - Does the subpoena or court order we have been served with ask for a disclosure that involves PHI?
 - If so, is the disclosure required by law, an exemption that is spelled out in simple language in 45 C.F.R. 164.512?
 - If so, then HIPAA allows the covered entity to comply with the subpoena or court order.
- What follows is our effort to show how much more complicated a covered entity’s process would become under the proposed rule each time it is 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.⁵⁸ 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

⁵⁸ *Id.* § 164.502(a).

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 poorly-defined terms alone will cause confusion. But HHS’s 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 by § 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 says that “reproductive health care” can be “related to reproductive organs” and defines “reproductive health care” to include “care . . . related to the reproductive health of the individual,”⁵⁹ and given that the definition of “care” includes “regard coming from desire or esteem,”⁶⁰ 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)?⁶¹ 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 “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?
- 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

⁵⁹ *Id.* § 160.103.

⁶⁰ Care, Merriam-Webster, <https://www.merriam-webster.com/dictionary/care>.

⁶¹ The Surplusage Canon (*verba cum effectu sunt accipienda*) would seem to necessitate this possibility.

⁶² *Ibid.*

reproductive health care,” the standard set out in § 164.502(a)(5)(iii)(D)?⁶³ 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”⁶⁴ on how to determine whether a proposed use or disclosure of PHI is permitted under 45 CFR § 164.512. *Not one covered entity in a thousand would agree with HHS’s claim.*
- 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 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.

⁶³ *Ibid.*

⁶⁴ 88 Fed. Reg. at 23509.

- 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:
 - 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.”⁶⁵
 - 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?
 - Can HHS or OIRA claim with a straight face that this aspect of the proposed rule would make complying with HIPAA less confusing for covered entities?
- 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

⁶⁵ 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).

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 itself 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*.
- As shown below, however, the proposed rule makes this extraordinarily hard.

(i) 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.”⁶⁶ 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.”⁶⁷ 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.
- 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.”⁶⁸ It claims that the Proposed Rule would not “disrupt longstanding state or Federal child abuse reporting requirements

⁶⁶ 45 C.F.R. § 164.502(a)(5)(iii)(A)(1).

⁶⁷ *Id.* § 164.502(a)(5)(iii)(A)(2).

⁶⁸ 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.*

that apply to regulated entities.”⁶⁹ 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.

(ii) 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?
- 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.

⁶⁹ *Id.* at 23527.

- 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.

(iii) 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.”⁷⁰ 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.”⁷¹
 - 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.

⁷⁰ *Id.* at 23522.

⁷¹ *Id.* at 23520.

- 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.
- 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.

(iv) 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.

4. 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.

- 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 aggress position on abortion and other hotly-debated issues related to “reproductive health care;”⁷² 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.

⁷² See Rachel N. Morrison, *How Democrats Set The Stage In 2023 For An LGBT Onslaught In 2024*, Federalist, Jan. 9, 2024, <https://thefederalist.com/2024/01/09/how-democrats-set-the-stage-in-2023-for-an-lgbt-onslaught-in-2024/> (“In 2023, Democrats doubled down on their commitment to radical gender ideology. Here’s how their agenda threatens to pan out in 2024.”).

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

⁷³ 88 Fed. Reg. at 23516.

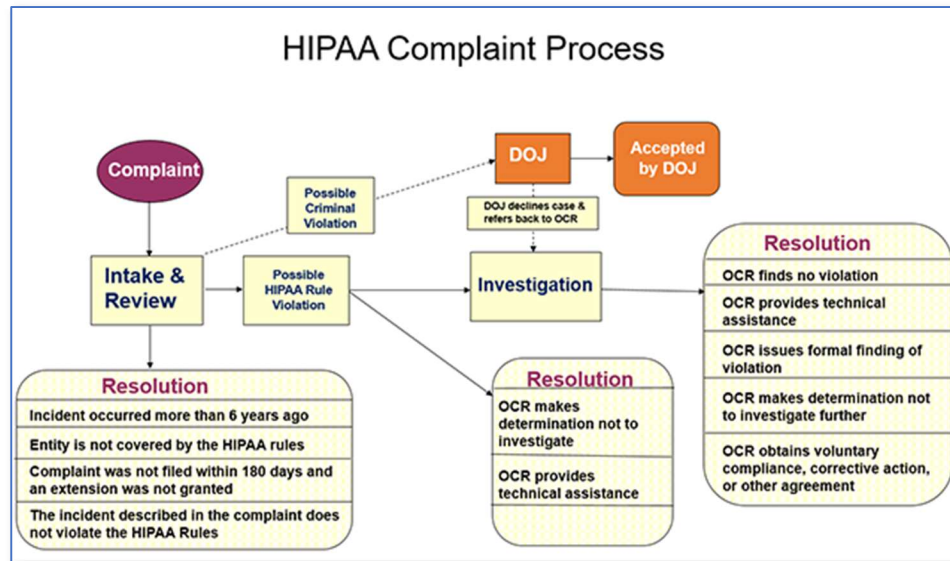
⁷⁴ *Id.* at 23519.

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-ro-e-response>.

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

- 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



- 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

5. The Proposal must address its federalism implications.

- As you are familiar, Executive Order 13132 from the Clinton Administration⁸¹ establishes certain requirements that an agency must meet when it issues a rule that

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

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>.

⁸¹ Exec. Order 13,132, Federalism, 64 Fed. Reg. 43255 (Aug. 10, 1999).

imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

- Section 3(c) of the EO states that “with respect to Federal statutes and regulations administered by the States, the national government shall grant the States the maximum administrative discretion possible.”
- Section 3(d) explains how to implement policies that have federalism implications. Specifically, agencies “*shall*” (1) “encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States,” (2) “where possible, defer to the States to establish standards,” and (3)/(4) consult with States and officials.
- Executive Order 12866⁸² (§ 6(a)(3)(B)) also directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions.
- HHS’s proposal will clearly have federalism implications:
 - It would make it unlawful for covered entities to comply with legitimate law enforcement efforts to enforce state laws that advance legitimate state interests.
 - Even when the proposed rule does not clearly prohibit covered entities from complying with state-issued subpoenas, court orders, and discovery requests, it will have the predictable (and likely intended) effect of intimidating covered entities out of cooperating with law enforcement investigations.
 - The federalism implications are heightened because, as the Supreme Court affirmed in *Dobbs*, “health and welfare laws” (such as laws restricting abortion and gender transitions on minors) are “entitled to a strong presumption of validity” and “must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests.”⁸³
 - Twenty-three states have passed laws restricting or banning the provision of “gender transition” interventions on minors and almost all of these have been passed since HHS published this proposed rule. Around 21 states have passed laws restricting abortion.⁸⁴
- For all these reasons, it is incumbent on HHS to do a much better job than it does in the proposed rule to speak clearly about its intentions and how it expects the Privacy Rule to work together with state laws.
 - The public deserves clarity on this issue.
- Covered entities have an even more focused need for clarity on this issue.
 - What does HHS expect them to do?

⁸² Exec. Order 12,866, Regulatory Planning and Review, 58 Fed. Reg. No. 190 (Sept. 30, 1993).

⁸³ 597 U.S. at 221 (cleaned up).

⁸⁴ Tracking Abortion Bans Across the Country, NY Times (Jan. 8, 2024), <https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html> (“Twenty-one states ban abortion or restrict the procedure earlier in pregnancy than the standard set by *Roe v. Wade*.”).

- How are hospitals and medical professionals supposed to balance their legal obligations to cooperate with legitimate law enforcement investigations against their fear that an aggressively pro-abortion and pro-“gender transition” administration will use these vague regulations against them?
- In addressing the federalism concerns that advance legitimate state interests in protecting unborn human life from abortions and protecting minors from irreversible gender transition procedures, HHS must acknowledge and take into consideration that no federal law asserts an interest in providing access to either abortion or gender transition procedures.

6. HHS must square its rule with the major questions doctrine.

- HHS’s proposed rule raises serious questions under the major questions doctrine. The Supreme Court most recently spoke to this doctrine in *Biden v. Nebraska*, where it expressed its “concerns over the exercise of administrative power”⁸⁵ and clarified the criteria courts and federal agencies must use when determining whether Congress has delegated authority to a federal agency to address “questions of deep economic and political significance.”⁸⁶
- The major question doctrine is rooted in the basic premise that Congress normally “intends to make major policy decisions itself, not leave those decisions to agencies.”⁸⁷ Or, as Justice Breyer once observed, “Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters [for agencies] to answer themselves in the course of a statute’s daily administration.”⁸⁸
- The major questions doctrine is also rooted in the separation of powers, a basic feature of the federal government. Most relevant here, the Constitution vests Congress with “[a]ll legislative Powers.” Art. I, § 1.⁸⁹
- Under the major questions doctrine, it would be absurd for HHS to claim that Congress, in passing HIPAA, intended to interfere with legitimate law enforcement activity related to laws that protect minors and unborn humans from coercion and violence.
- Furthermore, in the wake of *Dobbs* and the Court’s decision to return the issue of abortion “to the people and their elected representatives,”⁹⁰ and in light of vastly different state pro-life laws and minor gender transition procedure laws, whether the federal government should interfere with state laws in these areas is certainly a major question of vast political and economic significance—one that Congress must explicitly speak to under the major questions doctrine.

⁸⁵ 143 S. Ct. 2355, 2372 (2023).

⁸⁶ *Id.* at 2375.

⁸⁷ *United States Telecom Assn. v. FCC*, 855 F.3d 381, 419 (CA DC 2017) (Kavanaugh, J., dissenting from denial of reh’g en banc).

⁸⁸ S. Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 370 (1986).

⁸⁹ See also *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (explaining that the major questions doctrine rests on “both separation of powers principles and a practical understanding of legislative intent”).

⁹⁰ *Dobbs*, 597 U.S. at 302.

- To the extent that HHS’s arguments that it can legally issue such expansive regulations under HIPAA rely on *Chevron* deference, HHS should wait for the Supreme Court’s decisions in *Relentless* and *Loper Bright*. The Supreme Court just heard oral argument in these cases on January 17, 2024.⁹¹
 - At issue in these cases is whether the Supreme Court should “overrule *Chevron v. Natural Resources Defense Council*, or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency.”⁹²
 - Depending on how the Court rules, these cases could have major impact on the deference given to HHS’s efforts to use HIPAA to advance its interests in abortion and “gender transitions.”

7. HHS should given an account for how much these complicated rules would cost the public.

- HHS is required to estimate the economic impact of proposed rulemaking.
- Given the complexity of these proposed rules, we submit that there are several categories of costs that HHS must attempt to estimate:
 - How many attorney hours will it take the average covered entity to wrestle with its new and complicated obligations under these proposed rules? What is the estimate cost of this investigation in legal fees?
 - How much time would it take covered entities to make the administrative changes necessary to take this legal advice into account and make the required changes to its procedures in response to requests for PHI?
 - How many attorney hours will it take the average covered entity to respond to individual requests for PHI under these proposed regulations? What is the estimated cost in legal fees? How does this compare to the time and cost covered entities spend complying with HIPAA’s privacy rule under current regulations?
 - What are the estimated legal fees and court fines that covered entities will incur when these proposed rules intimidate covered entities into refusing to comply with subpoenas and court orders related to enforcing state health and wellness laws?

⁹¹ See Amy Howe, *Supreme Court Likely to Discard Chevron*, SCOTUSblog (Jan. 17, 2024), <https://www.scotusblog.com/2024/01/supreme-court-likely-to-discard-chevron/>.

⁹² Order, *Loper Bright Enterprises v. Raimondo*, No. 22-451 (May 1, 2023).

Conclusion

We urge OIRA to ensure that the statutory and regulatory process is upheld, that HHS has a legal basis to pursue new rulemaking, that HHS's final rule actually makes the identified problem better, and more broadly that this rulemaking satisfies HHS's obligations under the Constitution, the Administrative Procedure Act, and all other relevant legal authority.

For all the reasons set out above, we are confident that an objective observer would conclude that the proposed rule does not satisfy any of these legal requirements. As such, we urge HHS to withdraw and scrap the proposed rule.