Through this proposed rule, HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23506 (April 17, 2023) (the "Proposed Rule"), the Biden administration seeks to disrupt well-established federal privacy law standards, interfere with the proper exercise of state's public health powers, and undermine the final authority of a U.S. Supreme Court ruling. The proposed rule disregards the sanctity of human life; harms children and adults who are victims of abuse; and imposes unnecessary and inappropriate costs on health care providers.

COMMENTS

1. The Proposed Rule is unnecessary, as HIPAA currently strikes an appropriate balance between the legitimate interests at issue here.

As an initial matter, the Proposed Rule is unnecessary, since HIPAA and its implementing rules already strike an appropriate balance between privacy concerns and public health interests. In the words of HHS in its Summary to the HIPAA Privacy Rule, the Privacy Rule "strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing" and "is designed to be flexible and comprehensive." HIPAA presently strikes this balance without reference to controversial social issues, and it would be a careless misstep to disrupt this balance and introduce inflexibility, exchanging situational sensitivity for federal fiat, by placing a heavy thumb on the scale in support of one side in a contemporary social controversy. Engagement with controversies is better left to the legislative and judicial processes.

The Proposed Rule represents a solution in search of a problem--while fostering and safeguarding "the trust between individuals and health care providers" is a valid and worthwhile goal, that goal is already furthered by existing HIPAA rules. PHI is subject to disclosure in thoughtfully reasoned circumstances, including when required by law, in certain judicial and administrative proceedings, and for identified law enforcement purposes. This is despite the fact that HIPAA recognizes the interest in privacy that patients have in *all* PHI. To permit or require disclosure is not to deny a patient's compelling interest in privacy, or the essentiality of a positive, trusting relationship between patients and their providers, but instead to recognize the basic fact that there are often other interests present. It is difficult to imagine a valid justification for singling out reproductive health records in such a way, when even mental health records lack such protection. Indeed, only a subset of mental health records, namely psychotherapy notes, warrant special treatment--a special treatment far more narrowly tailored to the valid concerns inherent in the psychotherapist-patient relationship. Federal privacy laws also afford another category of records special protections, namely, substance abuse records. However, even records within this especially sensitive category are subject to exceptions, for example, for disclosure to law enforcement, reports to law enforcement, and court ordered disclosures. These special cases recognize the potential for heightened sensitivity; by longstanding convention and policy judgment, they do not

ignore the countervailing public interest in occasional disclosure. In each case, both where PHI may be due special protections (whether with regard to psychotherapy notes or drug and alcohol addiction records), and where it is due its "normal" (albeit still robust) protections, there has been a carefully reasoned determination that in some situations disclosure may be appropriate. The fact that in a post-*Dobbs* world, sensitive PHI may be disclosed under those particular circumstances already articulated under the Privacy Rule is not a bug, but rather a feature, of federal privacy law: competing interests may well exist with regard to the treatment of certain information, but HIPAA has already well defined the field in which those interests are to be resolved.

2. The Proposed Rule would improperly impede legal authorities, for while it purports to protect seekers of lawful abortions it is in fact structured to interfere with states' exercise of their lawful powers.

The Proposed Rule purports to seek to curtail "investigations or proceedings that chill access to lawful health care." What it is structured to do in fact, however, is to curtail the enforcement of state laws that seek to restrict or regulate abortion in a manner that differs from the policy decisions the rule-makers would themselves make. Put another way, it seeks to use HIPAA to impede certain forms of abortion regulation, usurping an authority that the Supreme Court locates in "the people and their elected representatives." The Proposed Rule reveals this purpose, for example, when it notes that "[s]ome states have already imposed criminal, civil, or administrative liability" in the realm of reproductive health care (and others may follow, noted in apparent alarm), implying that this is a trend to be circumvented. In doing so, the Proposed Rule ignores that a patient's right to privacy, valued though it may be, is not and never has been absolute under HIPAA: HIPAA's Privacy Rule also, as HHS has stated (through its Office for the Assistant Secretary for Planning and Evaluation), recognizes that public responsibility may require disclosure in order to protect public health, though this may limit the exercise of an individual's privacy right. Some states have indeed determined that the protection of public health requires the enactment and enforcement of certain laws. If it is true, as the Proposed Rule warns, that PHI may be sought in connection with "civil, criminal, or administrative investigations" related to lawfully provided reproductive health care, this fact does not give sufficient warrant to undermine the public health interests of the people and their elected representatives. Indeed, "in connection with" is an incredibly broad qualifier; if an investigation is commenced into an abortion provider's potential noncompliance with generally applicable medical standards in his or her state (e.g., failing to meet safety or professional requirements), the investigation would almost necessarily be "in connection with" a person seeking or providing reproductive health care, even if there are no limits in the particular state with regard to the legality of abortion. Indeed, the same could be said for investigations into an obstetrician's medical practice, which would be "in connection with" a person seeking or providing reproductive health care even if no abortions were involved.

The Proposed Rule places the burden of determining whether reproductive health care was lawfully provided not on investigators and other legal authorities but on health care providers and other regulated entities. Such regulated entities are not well positioned to make such a determination. Putting aside the added burden to providers, discussed in more detail below, this approach forcefully deputizes providers as investigators, requiring them to make legal findings which they are unsuited to make and for which they will often have insufficient evidence. Traditionally, lawfulness or unlawfulness is determined *after* an investigation by appropriate authorities in appropriate settings, rather than before. So should it be with regard to the determining the lawfulness of providing health care, such as the reproductive health care services at issue here.

The Proposed Rule also fails to provide sufficient guidance as to the appropriate means of determining where reproductive health care services take place. In various situations, the act of "obtaining" or "facilitating" health care may well cross state lines. If, for example, a minor is trafficked across multiple states, and an abortion is facilitated for her in one state, does the fact that the abortion may have been legal in that state, would the Proposed Rule limited the ability of regulated entities from providing the reproductive health care records to investigators into the trafficking? Such records may not be the only evidence investigators into such a crime would have; they would, no doubt, be highly compelling and relevant. Crimes often cross state lines, and likewise investigations. However, even investigations within a single state may be stymied by the Proposed Rule, as the third condition listed by the Proposed Rule makes clear. Investigations even within a strongly pro-abortion state would not be permitted to obtain relevant PHI from providers without establishing in advance that the care involved was impermissible under the law of the state. Normally establishing such facts is done pursuant to an investigation, rather than a precondition of the investigation proceeding.

The Proposed Rule also prohibits disclosures of PHI when an investigation is in connection with reproductive health care "protected, required, or authorized by Federal law." Well intentioned or not, the Proposed Rule here infringes on the highest expression of federal law, namely, that "[t]he Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion." Federal law recognizes that a State may have a legitimate interest in protecting the life of the unborn, and undermining those efforts by thwarting states' investigations into potentially unlawful conduct is an inappropriate exercise of the Department's rulemaking authority.

3. The Proposed Rule includes definitions that are ill-considered or inappropriate.

The Proposed Rule introduces certain definitions that are either inappropriate or overly broad. Under the first category is its new definition of "natural person" that "does not include a fertilized egg, embryo, or fetus." It cites 1 U.S.C. §8 for its basis in doing so, while ignoring that this authority is structured in an inclusive, rather than exclusive, way. That is, certain terms "include every infant member of the species homo sapiens who is born alive" but expressly affirms 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." While the impulse to reconcile terminology used in federal law is not an improper impulse, it should be noted that (1) the Proposed Rule does not do so, instead misapplying or artificially limiting the cited authority, and (2) a law that operates in the health care context should be all the more careful to base its definitions in scientific knowledge and to avoid adopting a discriminatory definition that could limit the rights of the individual. As an alternative, we suggest more closely tracking the definition in 1 U.S.C. §8, which appears to be the professed intent already, something like the following language from the statute itself: "the words 'person', 'human being', 'child', and 'individual', shall include every infant member of the species homo sapiens who is born alive at any stage of development. Nothing in this definition 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."

Similarly inappropriate is the Proposed Rule's engagement with the term "child abuse." Indeed, the Proposed Rule makes the incredible claim that, with reference to federal child abuse reporting laws, "the term 'child abuse' does not include activities related to reproductive health care, such as abortion." This ignores the fact that the proposed definition of "reproductive health care" is far broader than merely abortion: the Department would have it mean "care, services, or supplies related to the reproductive health of the individual." Thus, by the Proposed Rule's reasoning, "child abuse" would not include activities related to the reproductive health of the individual, i.e., would not include health care sought due to sexual abuse of a minor (whether or not it involved a pregnancy and/or an abortion). In the interest of protecting actual and potential victims of child abuse and in recognition of the fact that such child abuse is all too often sexual in nature, we recommend that the Department not exclude the seeking, obtaining, providing, or facilitating of reproductive health care from the term "child abuse." The alternative is to afford perpetrators of child abuse tools in their efforts to keep such abuse hidden.

The breadth of the definition of reproductive health care referenced above is indeed overbroad. It would cover not only abortion but all aspects of pregnancy, sterilization, surgeries on the reproductive systems, and more. As a result, it would greatly disrupt the careful balance already struck by HIPAA between individual interest in privacy and the public interest in certain disclosures--that is, this exception could swallow a large chunk of the rule. It is unclear why such a definition is needed, and our recommendation is to omit this definition entirely.

4. The Proposed Rule would help shield child abusers and other perpetrators of sexual crimes.

As discussed above, the Proposed Rule would stymie state public health investigators and other law enforcement actors in their efforts to prevent, address, and punish certain sexual crimes. As

noted, this is a clear risk when such crimes cross state lines, but the risk exists even within a single state, as investigations may not be able to obtain highly relevant evidence if such evidence is, loosely considered, "in connection with" the obtaining of reproductive health care. While the section above addresses this issue to some degree, it merits special attention in light of the prevalence of human trafficking and statutory rape in our nation. Such transgressions often go hand in hand. Providers risk being complicit in such conduct (morally, whether legally or not) when there is evidence of such abuse—such as a young girl's pregnancy—and they allow such evidence to remain out of sight.

The new paragraph (g)(5)(iii) of 42 CFR 164.502 exacerbates the interference into unlawful conduct introduced elsewhere by the Proposed Rule. This addition would prevent providers and other regulated entities from denying "personal representative status to a person, where such status would otherwise be consistent with state and other applicable law, primarily because that person facilitates or facilitated or provided reproductive health care for an individual. Unfortunately, there is no shortage of criminal activity that is arguably connected with or discovered through an abortion, such as incest, statutory rape, or trafficking, and more unfortunate still, such crimes are often committed by individuals who may meet state definitions of personal representative. Hindering state investigations into such matters serves no party but the violators.

5. The Proposed Rule would lead to increased costs and other burdens on health care providers and divert the resources of such providers from the provision of health care.

The Proposed Rule represents increased costs to providers, a class of actors already experiencing significant administrative costs and burdens that often interfere with their core purpose of providing health care to patients and meeting public health needs. The Proposed Rule identifies six categories of such quantifiable costs, including revising business associate agreements, developing new or modified policies and procedures, and revising training programs for workforce members, all together representing a first year estimated cost of $612 million. One additional burden not fully articulated in the Proposed Rule is the compliance cost of determining as a matter of law when the reproductive health care is lawful. Even for large providers who may have in-house legal staff, such analysis represents a cost; for those providers who must engage outside counsel, the costs are likely to be even more significant. The legal and other financial costs of such a determination are likely to be significant, particularly since the providers may not be privy to all the facts. Providers will generally lack the subpoena power and other investigative tools necessary to make such a determination with any sort of confidence, and may be caught between the Scylla and Charybdis of complying with the Proposed Rule and state law. Additionally, the patient-provider relationship may be threatened when a provider must explain to his or her patient that the patient's records had to be disclosed because the provider has determined that the patient broke the law (rather than giving the reason now, namely, that the records were simply requested by investigating public health authorities).

The Proposed Rule identifies suggested benefits while leaving them unquantified. This is no doubt in part because some of these identified benefits are likely to be unrealized, or worse, represent actual costs. For example, the Proposed Rule claims as a benefit "enhanced support for victims of rape, incest, and sex trafficking," but the policies it would adopt would in many cases interfere with such support and protection by assisting perpetrators in their efforts to conceal their conduct.

CONCLUSION

In summary, the Proposed Rule represents and unnecessary and unwelcome disruption of the appropriate balance that HIPAA strikes between privacy interests and public interests; interferes with the lawful exercise of legitimate state authority; includes or revises definitions in an ill-considered manner; and introduces significant burdens on health care providers while offering little to no identified benefits. For that reason, it is our recommendation that the Proposed Rule be rescinded or delayed for further careful consideration and comment.

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