



June 16, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: RIN Number 0945-AA20, Notice of Proposed Rulemaking, HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23506 (Apr. 17, 2023)

Dear Secretary Becerra:

The Attorneys General of Mississippi, Alabama, Alaska, Arkansas, Georgia, Idaho, Indiana, Kentucky, Louisiana, Missouri, Montana, Nebraska, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Texas, and Utah submit these comments opposing the Department of Health and Human Services' proposed rule, HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 Fed. Reg. 23506 (Apr. 17, 2023).

Last year, the Supreme Court held that abortion is a matter that is entrusted to "the people and their elected representatives" to address. *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022). Overruling precedent that took that authority away from the people, the Court returned the issue of "regulating or prohibiting abortion" to "the citizens of each State." *Ibid.* Since *Dobbs*, many States have adopted or maintained permissive approaches to abortion. Other States have taken steps—informed by the will of their citizens—to regulate or restrict abortion. State laws restricting abortion ubiquitously include provisions to protect a woman's life and commonly include exceptions in other circumstances as well. These laws advance "legitimate interests" in protecting "prenatal life," "maternal health and safety," and "the integrity of the medical profession." *Ibid.*

The Administration, however, has pushed a false narrative that States are seeking to treat pregnant women as criminals or punish medical personnel who provide lifesaving care. Based on this lie, the Administration has sought to wrest control over abortion back from the people in defiance of the Constitution and *Dobbs*.

The proposed rule here continues that effort. For over 20 years, HHS regulations have safeguarded the privacy of individual health information while permitting disclosure of information to state authorities to protect public health, safety, and welfare. The proposed rule would upset that careful, decades-old balance. The proposed rule defies the governing statute, would unlawfully interfere with States' authority to enforce their laws, and does not serve any legitimate need. Relying as it does on a false view of state regulation of abortion, the proposed rule is a solution in search of a problem. And it reflects the same distortion of basic legal rules and democratic principles that pervaded abortion matters for decades before *Dobbs*.

The Department should withdraw the proposed rule.

I. Background

A. HIPAA and the Privacy Rule

Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to “improve portability and continuity” and “simplify the administration of health insurance.” Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996). Among its many provisions, HIPAA directed HHS to develop “detailed recommendations on standards with respect to the privacy of individually identifiable health information” and to “promulgate final regulations containing such standards.” *Id.* § 264(a), (c)(1), 110 Stat. at 2033.

In 2000, HHS adopted Standards for Privacy of Individually Identifiable Health Information, known as the HIPAA Privacy Rule. 65 Fed. Reg. 82462 (Dec. 28, 2000). That Rule “address[es] the use and disclosure of individuals’ health information”—called “protected health information” or PHI. Summary of the HIPAA Privacy Rule 1, HHS Office for Civil Rights (May 2003), <https://bit.ly/43reEVj>. The Rule generally applies to regulated entities—“health plan[s],” “health care clearinghouse[s],” and certain “health care provider[s] who transmit[] ... health information in electronic form.” 45 C.F.R. § 160.102; *see id.* § 164.500. Its “major goal” “is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being.” Summary of the HIPAA Privacy Rule 1.

In adopting the Privacy Rule, HHS explained that “[t]he provision of high-quality health care requires the exchange of personal, often-sensitive information between an individual and a skilled practitioner.” 65 Fed. Reg. at 82463. “Vital to

that interaction is the patient’s ability to trust that the information shared will be protected and kept confidential.” *Ibid.* The Privacy Rule thus generally bars using or disclosing PHI without the individual’s authorization. 45 C.F.R. § 164.508(a)(1).

At the same time, HHS recognized that privacy interests must be balanced against “the public interest in using identifiable health information for vital public and private purposes.” 65 Fed. Reg. at 82472; *id.* at 82566 (“[W]e must balance individuals’ privacy interests against the legitimate public interests in certain uses of health information.”). The Privacy Rule thus sets standards for using and disclosing PHI in certain circumstances *without* an individual’s authorization. These include disclosures: “for a law enforcement purpose to a law enforcement official,” 45 C.F.R. § 164.512(f); “[i]n response to an order of a court” or “a subpoena, discovery request, or other lawful process,” *id.* § 164.512(e)(1)(i), (ii); “to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate [health care] oversight,” *id.* § 164.512(d)(1); and to a “public health authority ... for the purpose of preventing or controlling disease, injury, or disability,” including “the conduct of public health surveillance, public health investigations, and public health interventions,” *id.* § 164.512(b)(1)(i).

The Privacy Rule says that it generally preempts state law when it is “impossible to comply with both the State and Federal requirements” or state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives” of HIPAA. 45 C.F.R. § 160.202; *see id.* § 160.203. By its terms, however, the Privacy Rule does not preempt a state law that: is “necessary” “[f]or purposes of serving a compelling need related to public health, safety, or welfare, and ... [any] intrusion into privacy is warranted when balanced against the need to be served”; “provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention”; or “requires a health plan to report, or to provide access to, information for the purpose of ... the licensure or certification of facilities or individuals.” *Id.* § 160.203(a)(1)(iv), (c), (d); *see* 42 U.S.C. § 1320d-7.

B. The Biden Administration’s Approach To Abortion

On June 24, 2022, in *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228 (2022), the Supreme Court overruled its decisions recognizing a constitutional right to abortion and returned the issue of “regulating or prohibiting abortion” to “the citizens of each State.” *Id.* at 2284. Since then, some States have adopted or maintained more restrictive approaches to abortion; many other States have adopted or maintained permissive approaches to abortion.

Rather than respect the decisions of some States to regulate abortion, the Biden Administration has instead sought to wrest control over abortion back from the people and their elected representatives. The day *Dobbs* was decided, President

Biden decried “the grave consequences of [the] Supreme Court[’s] decision.” Fact Sheet: President Biden Announces Actions In Light of Today’s Supreme Court Decision on *Dobbs v. Jackson Women’s Health Organization*, The White House (June 24, 2022), <http://bit.ly/3DqTmwd>. He signed an executive order lamenting States’ regulation of abortion and directing federal agencies to “expand access to abortion care.” Protecting Access to Reproductive Healthcare Services, Exec. Order No. 14076, 87 Fed. Reg. 42053, 42053 (2022). He later signed a memorandum spotlighting his Administration’s efforts to “evaluat[e] and monitor[]” state laws “that threaten to infringe” claimed “Federal legal protections [for abortion].” Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, The White House (Jan. 22, 2023), <http://bit.ly/3kEZrPl>. In his State of the Union address, the President labeled state laws restricting abortion as barriers to be avoided. Remarks of President Joe Biden—State of the Union Address as Prepared for Delivery, The White House (Feb. 7, 2023), <http://bit.ly/3RHeAfn>.

Federal agencies have heeded the President’s call and pursued a nationwide regime of elective abortion in defiance of contrary decisions by the peoples’ representatives in many States. For example, in September 2022, the Department of Veterans Affairs reversed longstanding practice and adopted a rule allowing taxpayer-funded abortions for veterans and beneficiaries. *See* Reproductive Health Services, 87 Fed. Reg. 55287 (Sept. 9, 2022). The VA’s rule exceeds the agency’s statutory authority, intrudes upon traditional state authority, and obstructs States’ ability to enforce their laws on abortion. In January 2023, the Food and Drug Administration purported to authorize a nationwide mail-order elective-abortion-drug regime. *See* FDA, Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, <http://bit.ly/3kHmh8Q>. The FDA’s actions exceed the agency’s authority, defy federal criminal law, and undermine States’ ability to protect their citizens.

C. The Proposed Rule

The proposed rule here continues the Administration’s efforts to override state abortion laws. Published on April 17, 2023, the proposed rule—HIPAA Privacy Rule To Support Reproductive Health Care Privacy—would drastically reshape the existing HIPAA Privacy Rule. HHS has declared that the proposed rule is motivated by “concerns” about *Dobbs*. 88 Fed. Reg. at 23507; *see* HHS, HIPAA Privacy Rule Notice of Proposed Rulemaking to Support Reproductive Health Care Privacy Fact Sheet (Apr. 2023), <https://bit.ly/3WD1IcD> (“The proposed rulemaking is one of many actions taken by HHS in support of President Biden’s [executive orders] ... issued [after] *Dobbs*.”); HHS, HHS Proposes Measures to Bolster Patient-Provider Confidentiality Around Reproductive Health Care (Apr. 12, 2023), <https://bit.ly/3WdmOHL> (President Biden “call[ed] on HHS to take action to meet this moment and we have wasted no time in doing so.”) (statement of Secretary Becerra).

HHS acknowledges that the existing Privacy Rule “is balanced to protect an individual’s privacy while allowing the use or disclosure of PHI for certain non-health care purposes, including in certain criminal, civil, and administrative investigations and proceedings.” 88 Fed. Reg. at 23516. As HHS explained in the original Privacy Rule rulemaking, barring disclosure of PHI in such circumstances “would unduly jeopardize public safety and make many operations of the health care system impossible.” 65 Fed. Reg. at 82566. HHS also recognized that when a federal, state, or local law mandates such disclosure, “another public entity has made the determination that the public interests outweigh the individual’s privacy interests,” and the Privacy Rule would “not upset that determination.” *Ibid.*

HHS has now reversed course and proposes to remake the Privacy Rule.

First, the proposed rule would prohibit a regulated entity’s disclosure of PHI “for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care” in three general circumstances. 88 Fed. Reg. at 23552. Specifically, it would bar disclosure where the relevant “investigation” or “proceeding” concerns “reproductive health care” that is: provided “outside of the state where the investigation or proceeding is authorized and ... is lawful in the state in which it is provided”; “protected, required, or authorized by Federal law, regardless of the state in which [it] is provided”; or “provided in the state in which the investigation or proceeding is authorized and ... is permitted by the law of that state.” *Ibid.* The bar on disclosure would not be limited to investigations or proceedings involving the person who sought “reproductive health care.” Rather, it would apply to investigations or proceedings involving “*any person*” in connection with such “care.” *Id.* at 23532 (emphasis added).

Second, the proposed rule would require the recipient of a request for PHI “potentially related to reproductive health care” to obtain an attestation from the requesting entity before making a disclosure. *Id.* at 23553. The attestation must “verif[y]” that the request is not barred under the new prohibition on disclosing PHI related to “reproductive health care.” *Ibid.* The attestation requirement would apply to any request for PHI related to “reproductive health care” for health oversight, legal proceedings, law-enforcement purposes, or disclosures to coroners and medical examiners. *Ibid.* (citing 45 C.F.R. § 164.512(d), (e), (f), & (g)(1)).

Third, the proposed rule would modify or add three defined terms to the Privacy Rule. It would redefine *person* to mean “a natural person (*meaning a human being who is born alive*), trust or estate, partnership, corporation, professional association ... , or other entity, public or private”; define *public health* (as in “public health surveillance,” “public health investigation,” and “public health intervention”) to mean “population-level activities to prevent disease and promote health of populations”; and define *reproductive health care* to mean “care, services, or supplies related to the reproductive health of the individual.” *Ibid.* (emphasis reflects new text). *Public health* would exclude “uses and disclosures [of PHI] for

[a] criminal, civil, or administrative investigation ... or proceeding” about “reproductive health care.” *Ibid.* HHS says that *reproductive health care* should be “interpreted broadly and inclusive of all types of health care related to an individual’s reproductive system” or “reproductive organs,” “regardless of whether the health care is related to an individual’s pregnancy or whether the individual is of reproductive age.” *Id.* at 23527.

The proposed rule would largely jettison the Privacy Rule’s stated limitations on preemption of state law. HHS claims that the proposed rule would preempt any state law “requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process” in “any type of legal or administrative investigation or proceeding.” *Id.* at 23532. This would cover “law enforcement investigations, third party investigations in furtherance of civil proceedings, state licensure proceedings, criminal prosecutions, ... family law proceedings,” and private civil suits authorized by state law “against an individual or health care provider who obtained” or “provided” “a lawful abortion.” *Ibid.*

II. The Proposed Rule Is Unlawful And Should Be Withdrawn

As described above, the proposed rule would bar certain disclosures of PHI to state or local agencies conducting a “criminal, civil, or administrative investigation or proceeding ... in connection with” “reproductive health care.” 88 Fed. Reg. at 23552. The proposed rule would thus curtail the ability of state officials to obtain evidence of potential violations of state laws—even when requested under “a court order or other type of legal process.” *Id.* at 23532. The proposed rule has deep flaws and should be withdrawn.

A. The Proposed Rule Exceeds HHS’s Statutory Authority

The proposed rule exceeds the Department’s statutory authority. HIPAA authorizes HHS to set standards for protecting privacy in “health information.” The statute does not empower HHS to shield from authorities evidence of legal wrongdoing under state law based simply on a claimed connection to “health care.”

The proposed rule conflicts with HIPAA’s plain text. HIPAA authorizes HHS to adopt regulations establishing “standards with respect to the privacy of individually identifiable health information” for certain regulated entities. Pub. L. No. 104-191 § 264(c)(1), 110 Stat. at 2033. Under HIPAA, *health information* is information “created or received by” a regulated entity that “relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.” *Id.* § 262(a), 110 Stat. at 2022 (codified at 42 U.S.C. § 1320d(4)). *Individually identifiable health information* is “health information” that “identifies” or “can be used to identify” the individual. *Id.*, 110 Stat. at 2023 (codified at 42 U.S.C. § 1320d(6)). Central to both terms is the concept of *health*, which means, for example, “the condition of an organism

with respect to the performance of its vital functions” or “of, relating to, or engaged in welfare work directed to the cure and prevention of disease.” Webster’s Third New International Dictionary 1043 (1993); see The American Heritage Dictionary of the English Language 3d. ed. 3360 (1992) (*health* is “[t]he overall condition of an organism at a given time” or “[s]oundness, especially of body or mind; freedom from disease or abnormality”). Nowhere does HIPAA authorize HHS to shield from authorities information that is *not* “health information.” And the statute does not shield information that is evidence of legal wrongdoing under state law. Again, as HHS recognized in the Privacy Rule, HIPAA allows even some health information to be disclosed without an individual’s authorization—such as “for a law enforcement purpose to a law enforcement official,” 45 C.F.R. § 164.512(f), or “[i]n response to an order of a court,” *id.* § 164.512(e)(1)(i).

The proposed rule defies these principles. As noted, HIPAA rests on the understanding that effective healthcare “requires the exchange of personal, often-sensitive information between an individual and a skilled practitioner.” 65 Fed. Reg. at 82463. But HIPAA does not define the concept of healthcare (and related health information) to include activities that would violate state law. Yet, as HHS admits, the proposed rule here rests on the very proposition that *health information* protected from disclosure to legitimate state authorities includes information that a State believes is “evidence” of a violation of state law. 88 Fed. Reg. at 23516; see *id.* at 23547 (an individual’s health information “may be used as evidence against others”). No fair reading of *health information* permits that view. So the governing statute’s plain text does not allow the proposed rule.

That plain-text reading is fortified by bedrock rules of statutory interpretation. Congress is expected to “speak clearly when authorizing an agency” like HHS “to exercise powers of vast economic and political significance.” *Alabama Ass’n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (internal quotation marks omitted). This is especially true where, as here, an “administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.” *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173 (2001). Abortion has long been a contentious topic, and if Congress had wanted to delegate expansive authority over it to an agency, it would have said so. *Cf. West Virginia v. EPA*, 142 S. Ct. 2587, 2608 (2022) (rejecting an “expansive construction of [a] statute” because “Congress could not have intended to delegate such a sweeping and consequential authority in so cryptic a fashion”) (internal quotation marks omitted). HIPAA does not clearly express any intent to override States’ abortion laws.

Further, when “Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute.” *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (internal quotation marks and citation omitted). As discussed further below, *infra* Part II-B, the proposed rule trespasses on core state

functions—investigating violations of law and regulating professions for public safety and welfare. Nothing in HIPAA provides the necessary “clear statement” demonstrating Congress’s intent to “pre-empt the historic powers of the States” to the extent the proposed rule suggests. *Ibid.*

HIPAA itself shows that Congress knows how to—and does—limit the use or disclosure of health information when it wants to. For example, Congress expressly limited the use of health information in connection with investigations of “Federal health care offense[s].” Pub. L. No. 104-191 § 248(a), 110 Stat. at 2018. In such investigations, Congress provided that “[h]ealth information about an individual that is disclosed” pursuant to a federal administrative subpoena “may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual” “unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court.” *Id.*, 110 Stat. at 2019 (codified as amended at 18 U.S.C. § 3486(e)(1)). HHS can point to no similar statement by Congress in the context relevant here. This structural feature—particularly when combined with the statutory text and basic interpretive canons—dooms the proposed rule.

B. The Proposed Rule Defies The Constitutional Design

The proposed rule cannot be reconciled with our constitutional system. Under our system, States have broad authority to protect health and safety. And States have the corresponding authority (and duty) to address violations of their laws. The proposed rule trespasses on and interferes with state authority.

1. Under the Constitution, States—not the federal government—have the primary authority to protect the health, safety, and welfare of their citizens. *Bond v. United States*, 572 U.S. 844, 854 (2014) (“The States have broad authority to enact legislation for the public good—what we have often called a ‘police power.’ The Federal Government, by contrast, has no such authority.”) (internal citation omitted); *Hillsborough Cnty., Fla. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 719 (1985) (“[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.”). Every State has enacted laws to safeguard health and welfare, including on abortion. Investigating and addressing violations of those laws serves the public interest.

The proposed rule would interfere with States’ ability to obtain evidence that could reveal violations of their laws. This intrudes on core state authority. *Cf. Bond*, 572 U.S. at 858 (“Perhaps the clearest example of traditional state authority is the punishment of local criminal activity.”). And it far exceeds anything that Congress authorized in HIPAA. *See supra* Part II-A. The Department admits that the proposed rule has “federalism implications” because it directly affects “the states,” “the relationship between the National Government and states,” and “the

distribution of power and responsibilities among various levels of government relating to the disclosure of PHI.” 88 Fed. Reg. at 23550. But it claims that the rule is legitimate because, in circumstances where the proposed bar on disclosure would apply, “the state lacks any substantial interest in seeking the disclosure.” *Ibid.* As the Supreme Court recently made clear, however, States have a compelling interest in protecting life, health, and the medical profession in the context of abortion. *Dobbs*, 142 S. Ct. at 2284. And States’ authority to enact and enforce laws furthering those interests does not depend on HHS’s say so. The proposed rule is at odds with the Constitution.

HHS seeks to justify this intrusion into traditional areas of state authority by stressing that the proposed rule is limited to investigations or proceedings concerning “reproductive health care” that is “lawful in the state in which it is provided” or “protected, required, or authorized by Federal law.” 88 Fed. Reg. at 23552. The Department notes that it rejected a flat ban on using or disclosing PHI for *all* investigations or proceedings related to reproductive care “regardless of whether the care was lawful” due to “concern[s] that this uniform approach would have placed significant burdens on states’ abilities to enforce their laws.” *Ibid.* But the proposed rule has the very flaws that HHS claims it wished to avoid.

The proposed rule improperly empowers regulated entities (health plans, clearinghouses, and providers) to determine whether “reproductive health care” services are lawfully provided—and then to refuse compliance with state investigations and official proceedings based on that determination. *See id.* at 23531 (“[T]o determine whether the proposed rule would permit the use or disclosure of PHI, *the regulated entity* would need to determine whether the reproductive health care was provided under circumstances in which it was lawful to do so.”) (emphasis added). But regulated entities have neither the authority nor the competence to enforce state and local laws or to determine whether a violation of such laws has occurred. State law-enforcement personnel and government officials possess that authority, and by obstructing their ability to exercise it the proposed rule violates HIPAA and runs afoul of the constitutional design.

This infringement on state authority is exacerbated by the proposed rule’s sweeping definition of “reproductive health care.” When combined with the risk of “a potential [HHS] investigation and civil money penalty” for violating HIPAA regulations, *id.* at 23530—and the Administration’s stated hostility towards state regulation of abortion—the proposed rule would strongly incentivize regulated entities to refuse cooperation with state authorities even in circumstances where the proposed rule does not clearly apply.

2. The proposed rule also offends the constitutional design by undercutting state regulation of the medical profession and healthcare facilities. Such regulation is a core exercise of state police power and has been the norm for generations, as HHS itself admits. *See id.* at 23531 (“[S]tates determine the requirements for licensure of health care providers that furnish health care within their borders.”);

Barsky v. Bd. of Regents of Univ., 347 U.S. 442, 449 (1954) (“[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state’s police power.”).

The proposed rule applies to “investigation[s] into or proceeding[s] against *any person* in connection with ... reproductive health care,” 88 Fed. Reg. at 23552 (emphasis added), including medical personnel who are subject to state licensing requirements. *See id.* at 23532 (“[T]he proposed prohibition ... would apply to the use or disclosure of PHI against ... any other person, including an individual ... who may have ... provided ... or facilitated lawful reproductive health care.”). And the Department intends the proposed rule’s bar on disclosure of PHI to extend to “state licensure proceedings.” *Ibid.* The proposed rule would thus threaten States’ ability exercise their longstanding medical oversight authority.

That the proposed rule is ostensibly limited to circumstances where the relevant care was “lawful” is no answer. The conclusion whether such care is lawful depends on state authorities’ ability to make an informed determination based on relevant evidence, which the proposed rule undermines. Nor can the Department justify its approach by claiming that because States lack “the ability to set [licensing] requirements” that apply outside their borders, they “do not have the ability to permit or limit actors in another state from engaging in certain activities.” *Id.* at 23531. Medical providers can be (and often are) licensed to practice in multiple states. States have an interest in monitoring the conduct of medical personnel who are licensed under their laws but act out of state. *Cf. Dent v. West Virginia*, 129 U.S. 114, 123 (1889) (“Due consideration ... for the protection of society may well induce the state to exclude from practice those who have not such a license, or who are found upon examination not to be fully qualified.”). The proposed rule would obstruct that oversight.

3. The Department used to respect basic limits on federal authority. In the Privacy Rule, HHS recognized that HIPAA does not authorize a broad takeover of States’ regulation of health and welfare. The Privacy Rule thus disclaimed preemption of state laws in several circumstances, including where a state law “serv[es] a compelling need related to public health, safety, or welfare” or “provides for ... the conduct of public health surveillance, investigation, or intervention.” 45 C.F.R. § 160.203(a)(1)(iv), (c). No longer. Now, HHS would purport to override state authority to investigate or enforce state laws on abortion. HHS even goes as far as to propose defining the term *public health* to exclude investigations or proceedings concerning “reproductive health care,” *see* 88 Fed. Reg. at 23552. Besides obstructing States’ investigation of unlawful activity that may imperil public health, this would inhibit state health departments in fulfilling their lawful oversight functions.

As HHS once understood, the effective operation and enforcement of state health and safety laws serves a compelling need in protecting the public. By

thwarting States' enforcement of those laws, the proposed rule promises to "unduly jeopardize public safety." 65 Fed. Reg. at 82566.

C. The Proposed Rule Rests On Flawed Reasoning

HHS's attempts to justify the proposed rule reflect the Department's implausible reasoning, failure to meaningfully assess costs and benefits, and failure to consider important aspects of the problems it purports to address.

1. The proposed rule is a product of implausible reasoning. *E.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (An agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.") (internal quotation marks omitted). The proposed rule rests on the misguided assumption that it will be readily apparent or ascertainable whether particular "reproductive health care" services are lawfully provided. But the purpose of investigating is to determine whether lawbreaking has occurred. *Cf. Brogan v. United States*, 522 U.S. 398, 402 (1998) ("the investigation of wrongdoing is a proper governmental function" and "the very *purpose* of an investigation to uncover the truth"). And, of course, those who violate the law have an interest in concealing that fact.

HHS itself recognized this reality when adopting the Privacy Rule, which permits disclosures of PHI "for a law enforcement purpose to a law enforcement official." 45 C.F.R. § 164.512(f). That Rule makes clear that "law enforcement officials"—not regulated entities—"are empowered to prosecute cases as well as to conduct investigations" and that this authority extends to "*potential*" or "*alleged* violation[s] of law." 65 Fed. Reg. at 82493 (emphases added). HHS chose this definition over one limited to "investigation[s] or official proceeding[s] inquiring into a *violation of, or failure to comply with, any law*" because "when investigations begin, *often it is not clear that law has been violated.*" *Ibid.* (emphases added). The proposed rule would abandon this commonsense approach and thereby undermine legitimate state investigations into possible wrongdoing.

Consider an example. Suppose that state officials had reason to believe that an abortion provider deliberately performed an abortion in violation of state law, resulting in serious injury to the woman, and that the provider then falsified medical records and referred the woman to an out-of-state provider to cover it up. State officials would clearly have a basis to investigate that provider for "a potential violation of law." 45 C.F.R. § 164.103. But under the proposed rule, a regulated entity with relevant evidence could deny requests for that information based on its assumption that the "care" was "lawful" as reflected in the falsified records or as provided out of state. The proposed rule's broad definition of "reproductive health care" points up other problems as well. According to HHS, that term includes care "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.” 88 Fed. Reg. at 23527. That means that the proposed rule could inhibit States’ investigation of child abuse and other serious crimes.

2. The proposed rule also reflects HHS’s failure to soundly assess costs and benefits. *E.g.*, Regulatory Planning and Review, Exec. Order. No. 12866, 58 Fed. Reg. 51735, 51736 (Sept. 30, 1993) (Agencies must “propose or adopt a [significant] regulation only upon a reasoned determination that the benefits ... justify its costs.”). The Privacy Rule already provides substantial safeguards for protecting individual privacy. It generally bars disclosing PHI without the individual’s authorization. It permits such disclosure only in limited circumstances, such as in response to court orders. *See* 45 C.F.R. § 164.512. It also includes a “minimum necessary” standard for most disclosures of PHI, which requires regulated entities to “make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose” of a requested disclosure. *Id.* § 164.502(b). These protections apply to all individuals who seek or obtain healthcare.

The proposed rule departs from this careful balance without any sound basis. As HHS has long maintained, the Privacy Rule is the “result of balancing the interests of the individual in the privacy of their PHI with the interests of society in disclosures of PHI for non-health care purposes.” 88 Fed. Reg. at 23509. Disrupting that balance by preventing disclosure of PHI in response to valid law-enforcement requests, court orders, or oversight activities “would unduly jeopardize public safety and make many operations of the health care system impossible.” 65 Fed. Reg. at 82566.

HHS’s claim—following political pressure from the White House—that *Dobbs* justifies this result does not withstand scrutiny. *Dobbs* did not change the fact that duly authorized law-enforcement investigations and health-oversight activities serve the public interest. Indeed, to the extent that such matters concern abortion, *Dobbs* strengthens the case that they serve the public interest. The decision ensures that state abortion regulations now reflect the people’s will. Thus, HHS’s rationale for adopting the Privacy Rule’s current approach—that certain disclosures of PHI are appropriate because a “public entity has made the determination that law enforcement interests outweigh the individual’s privacy interests,” *id.* at 82682—applies with even greater force after *Dobbs*. HHS’s misunderstanding of these basic issues undermines the proposed rule.

3. The proposed rule reflects HHS’s improper reliance on political factors and “fail[ure] to consider an important aspect of the problem” that it purports to address. *Am. Clinical Lab’y Ass’n v. Becerra*, 40 F.4th 616, 624 (D.C. Cir. 2022). HHS suggests that States will weaponize *Dobbs* to investigate women for seeking lawful healthcare, particularly abortions. *E.g.*, 88 Fed. Reg. at 23521 (“[T]he primary reasons behind this rulemaking are the risks to privacy, patient trust, and health care quality that occur when it is the very act of obtaining health care that subjects an individual to an investigation.”). But the Department fails to back up

its fearmongering with evidence—from the period since *Dobbs* was decided, from the years before *Dobbs* when certain procedures (like late-term and partial-birth abortions) were unlawful in many States, or from the decades before *Roe v. Wade*, 410 U.S. 113 (1973), when “a substantial majority” of States “prohibited abortion at all stages except to save the life of the mother.” *Dobbs*, 142 S. Ct. at 2253.

Instead, the Department cites (at 88 Fed. Reg. at 23519 nn.169 & 170) a news article that mentions a state law used to prosecute illicit “drug consumption during pregnancy,” Talk of Prosecuting Women For Abortion Pills Roils Antiabortion Movement, Wash. Post (Jan. 11, 2023), and a report from an abortion-advocacy group claiming that “state actors are criminalizing pregnant women” and “non-binary, trans, and gender non-conforming people” “who become pregnant.” Pregnancy Justice, *Confronting Pregnancy Criminalization* 4 n.1 & 5 (July 2022). That report highlights pre-*Dobbs* cases involving pregnant women who knowingly subjected their unborn children to illegal drugs or alcohol. *Id.* at 5-17. The Department’s suggestion that protecting unborn children from illicit drug or alcohol abuse is somehow akin to “subject[ing] an individual to an investigation or proceeding” for “obtaining medically necessary health care,” 88 Fed. Reg. at 23521, lays bare the threadbare factual basis—and clear political motivations—for the proposed rule.

HHS also does not meaningfully address a crucial fact—the widespread reality of state laws expressly excluding pregnant women from liability in this context. *E.g.*, Miss. Code. Ann. § 41-41-45(4) (liability for unlawful abortions does not apply to “the pregnant woman”); N.D. Cent. Code Ann. § 12.1-52-02 (establishing liability for unlawful abortions “other than [for] the pregnant female upon whom the abortion was performed”). Indeed, the very source the Department cites to support its claim that States “criminalize ... reproductive health care,” 88 Fed. Reg. at 23510, acknowledges that abortion restrictions “almost always target[] providers rather than patients” and says that the pro-life movement “has long sought to treat women seeking abortions as ‘victims’ and not as targets for punishment.” Talk of Prosecuting Women (cited in 88 Fed. Reg. at 23510 n.33). And the Department’s bare assertion that state authorities will seek “disclosure of an individual’s PHI as a pretext” to undermine lawful care, 88 Fed. Reg. at 23507, is unbecoming of a federal agency, violates the “presumption of good faith” accorded to “government actors in their sovereign capacity and in the exercise of their official duties,” *Sossamon v. Lone Star State of Texas*, 560 F.3d 316, 325 (5th Cir. 2009), and fails to provide a reasoned basis for the proposed rule.

Last, the Department also claims that the proposed rule “may be necessary” because state enforcement of abortion restrictions after *Dobbs* “is likely to chill individuals’ willingness to seek lawful treatment or to provide full information to their health care providers.” 88 Fed. Reg. at 23507-08. Even if that dubious empirical claim were true (and HHS does not substantiate it), the proposed rule sweeps well beyond the Department’s stated goal to protect “individuals” who

“obtain[] health care.” *Id.* at 23521. As discussed, the proposed rule applies to “investigation[s] into or proceeding[s] against *any person* in connection with ... reproductive health care,” including medical personnel who are subject to state laws and licensing requirements. *Id.* at 23552 (emphasis added). Protecting providers who violate such laws and requirements under the guise of safeguarding “health information” is not a necessary or legitimate use of HIPAA authority.

D. Any Effort To Use The Proposed Rule To Advance Radical Transgender-Policy Goals Would Be Unlawful

The proposed rule focuses on abortion. But its broad definition of *reproductive health care* includes “health care 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.” 88 Fed. Reg. at 23527. Given its far-reaching and radical approach to transgender issues, the Administration may intend to use the proposed rule to obstruct state laws concerning experimental gender-transition procedures for minors (such as puberty blockers, hormone therapy, and surgical interventions). *See* Fact Sheet: Biden-Harris Administration Advances Equality and Visibility for Transgender Americans, The White House (Mar. 31, 2023), <https://bit.ly/43B8KBU> (detailing the Administration’s efforts to “expand[] access to gender-affirming health care” including “for children and adolescents”); Gender-Affirming Care and Young People, HHS Off. of Population Affs. 1-2 (Mar. 2022), <https://bit.ly/3oLDIHX> (detailing types of “gender-affirming care” for “children and adolescents,” including “puberty blockers” “during puberty,” “hormone therapy” in “early adolescence onward,” and “gender-affirming surgeries” on a “case-by-case [basis] in adolescence”) (capitalization omitted).

There would be many legal problems with using the rule in this way. First, HIPAA does not authorize it. As with abortion, the statute is silent on novel gender policies. Congress does not “typically use oblique or elliptical language to empower an agency to make a radical or fundamental change,” *West Virginia*, 142 S. Ct. at 2609 (internal quotation marks omitted)—which is what the proposed rule would (if used this way) do. *See ibid.* (noting presumption that “Congress intends to make major policy decisions itself, not leave those decisions to agencies”).

Second, the proposed rule does not provide adequate notice of so radical a policy change. HHS is required to provide the public with a meaningful “opportunity to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553(c). The relevant language here is not even contained in the text of the proposed rule itself but is buried—without explanation or analysis—in HHS’s gloss on its newly proposed definition of *reproductive health care*. *See* 88 Fed. Reg. at 23527. HHS has failed to enable meaningful comment by “disclos[ing] critical information justifying the proposal,” *GPA Midstream Ass’n v. DOT*, 67 F.4th 1188, 1197 (D.C. Cir. 2023), and “giv[ing] affected parties an opportunity to develop evidence in the record to support their objections to the

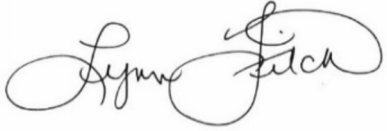
rule,” *Prometheus Radio Project v. FCC*, 652 F.3d 431, 449 (3d Cir. 2011); *see also Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (An agency must “describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making.”).

Last, the proposed rule fails to confront the federalism implications of such a policy. At least 20 States (more than a dozen in the past year alone) have acted to protect children from harmful and experimental gender-transition procedures. *See, e.g.*, Louisiana Lawmakers Pass Ban on Transition Care for Transgender Minors, N.Y. Times (June 7, 2023), <https://nyti.ms/43sxXxN>. More are sure to follow as the dangers of these procedures become increasingly apparent. *See, e.g.*, England Limits Use of Puberty-Blocking Drugs to Research Only, N.Y. Times (June 9, 2023), <https://nyti.ms/3J64tNW>; Increasing Number Of European Nations Adopt A More Cautious Approach To Gender-Affirming Care Among Minors, Forbes (June 6, 2023), <https://bit.ly/3qFd8As>; The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak, The Economist (Apr. 5, 2023), <https://econ.st/43vNPj9>. The proposed rule does not grapple with any of this.

* * *

HIPAA authorizes HHS to safeguard the privacy of individually identifiable health information. HIPAA does not authorize HHS to make broad policy judgments overriding or interfering with States’ decisions to protect “prenatal life,” “maternal health and safety,” and “the integrity of the medical profession.” *Dobbs*, 142 S. Ct. at 2284. The proposed rule would defy HIPAA, our constitutional system, and the Administrative Procedure Act. The Department should abandon the proposed rule.

Sincerely,



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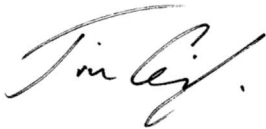
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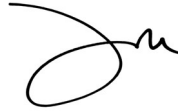
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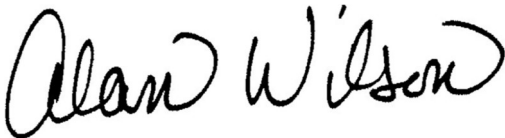
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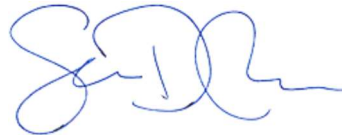
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