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Secretary Becerra,

I write as a former Director of the HHS Office for Civil Rights, as the nation's longest-serving HIPAA regulator (2017-2021), as a civil rights attorney, as a Harvard Law School graduate, and as a concerned citizen. I have thoroughly reviewed your Department's proposed HIPAA "Reproductive Health Care Privacy" (RIN Number 0945-AA20) and offer my comments.

We are a nation of laws. To the extent the proposed regulations can bind through imposition of substantial civil and criminal penalties, basic justice and due process require our health care professionals be told precisely and clearly what can get and cannot get them into ruinous trouble. The proposal's poor draftsmanship and confusing structure alone are enough to render it in violation of the Administrative Procedure Act, if not the Due Process Clause of the constitution. With its many cross-references, circular language, and internal contradictions, you cannot finalize this rule without violating the APA due to insufficient notice to covered entities as to exactly what conduct is prohibited and allowed.

Moving from form to substance, things unfortunately get worse. The proposal does not present evidence of real-world harm following the Supreme Court decision in the *Dobbs* case to justify the proposed changes. Rather, it uses speculation about possible future investigations as a pretext for the real goal of this proposed rule, which you, Mr. Secretary, have made abundantly clear.

On the day *Dobbs* was decided you said:

Today's decision is unconscionable. Abortion is a basic and essential part of health care – and patients must have the right to make decisions about their health care and autonomy over their own bodies. For decades, both as a member of Congress and as California's Attorney General, I have stood with people around the country to fight for reproductive freedom for everyone, no matter who you are, where you live or how much you make. At the Department of Health and Human Services, we stand unwavering in our commitment to ensure every American has access to health care and the ability to make decisions about health care -- including the right to safe and legal abortion, such as medication abortion that has been approved by the FDA for over 20 years. I have directed every part of my Department to do any and everything we can here. As I

have said before, we will double down and use every lever we have to protect access to abortion care.¹

We have seen this type of “massive resistance” to a landmark civil rights precedent before.² Then as now, politically motivated attempts to thwart the law of the land are not a legitimate or lawful basis for rulemaking. *Dobbs* restored the ability of legislatures at all levels to protect human beings in the womb from destruction. HIPAA simply cannot be drafted to get in their way without doing violence to federalism and the rule of law. The Department’s proposal is arbitrary, capricious, and would create intolerable conflicts with law. For these reasons and those discussed further below, this rulemaking should be abandoned in its entirety.

The Stated Rationales for Department Action are Defective

If there is one overarching fact that renders this rulemaking arbitrary, capricious, and unlawful it is this—the Department explicitly denies that unborn persons are persons protected under HIPAA even though they are undeniably living beings that receive health care, generate PHI, and are recognized as humans under HIPAA *by statute*.

The Department nevertheless argues that “The Department understands 1 U.S.C. 8 to provide a definition of ‘person’ and ‘child’ that is consistent with the Department’s understanding of that term, as it is used in the SSA, HIPAA, and the HIPAA Rules and does not include a fertilized egg, embryo, or fetus.”³ The Department is flatly wrong. 1 U.S.C. § 8 says that “Nothing 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.” (emphasis added). The Department is improperly relying on this statute to contract the legal status of unborn children in relation to state law and federal law. The Department is being disingenuous when it says that “The Department is not opining on whether any state law confers a particular legal status upon a fetus,” and that it “instead cites to this statute to define the scope of the right of privacy that attaches pursuant to HIPAA.”⁴ The Department is most certainly attempting to preempt state law on personhood. Although HIPAA usually preempts state law, the HIPAA Regulations specifically exempt certain state definitions and laws on matters highly relevant. Specifically, § 160.2053(a)(2)(C) *requires* the Department to recognize, and not preempt:

The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

¹ HHS Secretary Becerra's Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization*, June 24, 2022, (available at <https://www.hhs.gov/about/news/2022/06/24/hhs-secretary-becerras-statement-on-supreme-court-ruling-in-dobbs-v-jackson-women-health-organization.html>).

² “If we can organize the Southern States for massive resistance to this order [*Brown v. Board of Education*], I think that in time the rest of the country will realize that racial integration is not going to be accepted in the South.” Harry F. Byrd, United States Senator (D) from Virginia. Newport News Daily Press, “Byrd Calls for ‘Massive’ Resistance to Integration,” February 26, 1956.

³ 73 FR 23523.

⁴ 73 CFR 23523 at n.193.

Perhaps seeing the obstacle to its attack on *Dobbs*, the Department proposes to add an extremely curious new definition of “public health” but only as applied to “public health surveillance,” “public health investigation,” and “public health intervention.”⁵ More suspicious still, it proposes to redefine these terms to exclude “criminal, civil, or administrative investigation” against a person, or for the identification of any person, “in connection with obtaining, providing, or facilitating reproductive health care.”⁶ There is no rational reason to exclude abortion, not to mention all reproductive health, entirely from state public health oversight or investigation. The proposed amendment to § 160.103 renders § 160.2053(a)(2)(C) and § 164.512(b)(1)(i) dead letters with respect to one of the single most important health issues that any state faces—the preservation of the lives of their youngest and most vulnerable children.

The Supreme Court in *Dobbs* held that state and the federal governments are free to once again recognize unborn children as full legal persons, just as America held overwhelmingly for all of its pre-*Roe* history.⁷ The proposal instead seeks to create a special, irrational, carve-out just for “reproductive health” in an attempt to reimpose parts of *Roe* by outlawing, to the maximum extent possible, cooperation with any state government action aimed at saving unborn children from death through abortion.

If the Department thinks it can achieve this through such regulatory tricks, it is mistaken. The provision at issue does not lie within the Secretary’s regulatory discretion. Rather, respect for state sovereignty on these matters is required by Congress. 42 U.S. Code § 1320d–7(b) provides:

Public health

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

In the face of this clear injunction, the Department cannot redefine statutory terms to gerrymander out the single most important health surveillance, investigation, and intervention tools pro-life states have within their sovereign power. I speak here of states’ compelling interests in protecting tens of thousands of real human lives that the Department wants to erase regulatorily so they may be more easily eradicated physically.

⁵ See proposed § 160.103.

⁶ *Id.* I have provided a paraphrase because the full proposed text, as quoted in this footnote, is akin to a word snake eating its own tail. “Such activities do not include uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care, or for the identification of any person in connection with a criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care.”

⁷ *Dobbs v. Jackson*, 597 U. S. ____ (2022) (“abortion had long been a crime in every single State. At common law, abortion was criminal in at least some stages of pregnancy and was regarded as unlawful and could have very serious consequences at all stages. American law followed the common law until a wave of statutory restrictions in the 1800s expanded criminal liability for abortions. By the time of the adoption of the Fourteenth Amendment, three-quarters of the States had made abortion a crime at any stage of pregnancy, and the remaining States would soon follow. *Roe* either ignored or misstated this history.”).

Perhaps most definitively, Congress prevented the Department from overriding a state’s determination of what counts as a human “birth,” a human “death,” and “child abuse.” The Department has no authority to tell states they cannot define the contours of these terms for its own public health investigations and must instead yield to HHS’s flipped position.⁸

One of the more pernicious consequences of erasing unborn children from HIPAA’s definition of person is related to § 164.512(j)(1)(i), which allows disclosures “necessary to prevent or lessen a serious and imminent threat to the health or safety of a person.” Such disclosures are effectively outlawed under HIPAA when it comes unborn children, whether the threat is from a mother abusing drugs while 9 months pregnant, or from cases where a person seeks to get an abortion in a state where it is clearly illegal. While the proposal purports to limit its reach only to states where abortion is illegal, under its proposed and thoroughly confusing changes to § 164.502,⁹ the definitional effects spillover to everywhere “person” appears in the HIPAA.

More fundamentally, the Department’s proposal turns on the false assertion that, in the case of a pregnant woman, the mother is the only “person” that has any interests at stake under HIPAA. This goes counter to established Department practice. Indeed, the very first enforcement action under the OCR Right of Access Initiative involved an \$85,000 settlement payment to OCR after the covered entity was found to have wrongfully deprived a mother of her child’s fetal heart monitor records. As HHS OCR stated in a press release at the time, “This right to patient records extends to parents who seek medical information about their minor children, and in this case, a mother who sought *prenatal health records about her child.*”¹⁰

Moreover, as noted in the preamble,¹¹ the Privacy Rule was amended by the Genetic Information Nondiscrimination Act of 2008 (GINA). GINA requires that:

genetic information concerning an individual or family member of an individual shall—

- (1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and
- (2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

42 U.S.C. 2000ff-8.

⁸ HHS under the previous administration recognized the clear scientific fact that every human life begins at conception and is worthy of protection and recognition as a human person. See HHS Strategic Plan, 2018 (“HHS accomplishes its mission through programs and initiatives that cover a wide spectrum of activities, serving and protecting Americans at every stage of life, beginning at conception.”) <https://aspe.hhs.gov/sites/default/files/documents/feac346aca967bfadc446398679e14ec/hhs-strategic-plan-fy-2018-2022.pdf>.

⁹ 73 CFR 23552.

¹⁰ OCR Settles First Case in HIPAA Right of Access Initiative (September 9, 2019) (emphasis added) <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>.

¹¹ 73 FR 23507 at n.1.

Accordingly, the Privacy Rule states that protected health information includes genetic information, which specifically includes, the genetic information of:

- (i) A fetus carried by the individual or family member who is a pregnant woman; and
- (ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

45 CFR § 160.103

Thus, HIPAA itself acknowledges that *a child's* PHI is protected whether that child is inside or outside of the womb, born or unborn.

This fact makes the Department's citation to the Emergency Medical Treatment and Active Labor Act (EMTALA)¹² particularly ironic given that EMTALA itself requires stabilization and treatment of a mother in distress and "the unborn child."¹³ Finally, the National Childhood Vaccine Injury Act also covers the unborn child independently for vaccine injuries due to maternal vaccination.¹⁴

The Department Supports its Proposal with Speculation Instead of Relevant Evidence

Contrary to evidence and common sense, the proposal aims to end a "chill" that is allegedly preventing women from obtaining abortions post *Dobbs*.¹⁵ But not just any abortions. The Department's argument rests specifically on a mythical fear of prosecution or suits against women who have abortions in states where they are *100% legal* by the proposal's own terms. This fear is supposedly dissuading some unknown number of women from seeking out abortions which is leading to unknown negative health outcomes for an equally unknown, but certainly smaller, subset of these women.¹⁶ Because the Department presents a near total lack of substantiation for each of these claims,¹⁷ its proposal is arbitrary and capricious.

¹² 42 U.S.C. 1395dd, cited at 73 CFR 23531.

¹³ *Id.*

¹⁴ 42 USC 300aa-11.

¹⁵ See e.g., 73 FR 23507, 23508, 23529 (discussing the alleged "chill" on abortion and how proposal would eliminate it).

¹⁶ 73 FR 23507-23508; 73 FR 23546-23547 (Regulatory Impact Analysis).

¹⁷ The Department's repeated citations to speculative news articles and introduced but never passed bills do not constitute competent evidence. See e.g., 73 FR 23507 at n.11, 73 FR 23519 at n.163, and 73 FR 23520 at n.171. Nowhere does the preamble point to actual prosecutions in states that protect unborn life of women who received legal abortions in other states. The Department's only first-hand account that seemed potentially relevant turned out to be of a *Texas doctor* who irrationally falsified records to hide evidence of a legal abortion performed by another doctor *in another state*, thereby increasing, not diminishing the odds of an investigation based, not on abortion, but on falsifying medical records. 73 FR 23519. If this is the best evidence, it is no evidence at all. Moreover, reliable statistical evidence cuts exactly the other way. Despite numerous states now protecting life in law, their diminished abortion figures have been almost entirely offset by abortions increases in states where they are legal. In fact, despite approximately 20 states enforcing significant life protections the overall number of abortions in the nine months after *Dobbs* went down by only 24,290 (32,388 annualized) out of an annual total of approximately 930,000 (as of 2020) or approximately 3.5%. See Guttmacher Institute, Abortion incidence and service availability in the United States, 2020 (November 2022). <https://onlinelibrary.wiley.com/doi/10.1363/psrh.12215>; The Dobbs Divide, FiveThirtyEight (June 15, 2023) <https://fivethirtyeight.com/features/abortion-trend-after-dobbs/> The states where abortion remains legal have

Another major defect of the proposal concerns a conspicuous absence. Namely, the lack of any valuation or consideration of the worth and health of the unborn babies whose lives will be ended in greater numbers if the proposal goes into effect. The proposal is frank about wanting to impede investigations, both civil and criminal, into abortions. Presumably the proposal, if finalized, would have some effect on increasing the number of children lost to abortions, which must be included in the cost-benefit analysis. Their health matters too.

The Department makes much about HIPAA's clearly appropriate goals of creating a positive, trusting relationship between individuals and their health care providers. It even cites the original Hippocratic Oath which "required physicians to pledge to maintain the confidentiality of information they learn about their patients"¹⁸ but, illustrative of the larger problems with the proposal, omits the part of the Oath which reads "I will give no sort of medicine to any pregnant woman, with a view to destroy the child."¹⁹

The proposal notes that at the time HIPAA's general privacy standards were promulgated, HIPAA adequately protected information related to reproductive health care,²⁰ even though partial birth abortion had been outlawed nationally for many years. Thus, "based on settled Federal constitutional law in 2000, the Department did not see a need to treat uses or disclosures of PHI related to reproductive health care, such as information about a pregnancy termination, differently from other uses or disclosures of PHI related to other categories of health care."²¹ The burden is on the agency to prove how going from a regime where abortion was mostly legal nationwide to one where it is mostly legal in most states, endangers the privacy interests of people in the states where abortion remains legal. To state the proposition is to answer the question. Given our federal system it logically cannot be done because states do not have jurisdiction to enforce their laws out of state.

The Proposed Rule Would Create Health Care vs Non-Health Care Categorical Rules that are Arbitrary and Not Supported by the HIPAA Statute

The Department describes the purpose of the proposed rule as follows: "Based on information the Department has received in recent months,²² we believe it may be necessary to modify the Privacy Rule to avoid the circumstance where an existing provision of the Privacy Rule is used to request the use or disclosure of an individual's PHI as a pretext for obtaining PHI related to reproductive health care for a non-health care purpose where such use or disclosure would be detrimental to any person."²³

dramatically increased their abortion rates, which demonstrates that people are overcoming whatever inconveniences or additional travel costs cross state abortion entails and are not being held back by "litigation fear" as the NPRM suggests. Id.

¹⁸ 73 FR 23516.

¹⁹ Hippocratic Oath – Classic, McCollough Scholars, University of Alabama <https://mccolloughscholars.as.ua.edu/hippocratic-oath-classic/>.

²⁰ 73 FR 23518.

²¹ Id.

²² Be advised, if the rule is finalized, you are required to identify and include all the "information" you claim to have received that formed the justification for the NPRM as of April 17, 2023 (the date of the NPRM).

²³ 73 FR 23507.

This statement implies that HIPAA’s statutory purposes or its Rules are organized around a “health care” (permitted) and “non-health care” (prohibited/restricted) dichotomy, but this is a false impression. The HIPAA statute, upon which the entirety of the HIPAA Rules depend, says nothing of the sort:

Each person described in section 1320d–1(a) of this title who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards—

(A) to ensure the integrity and confidentiality of the information; [and]

(B) to protect against any reasonably anticipated—

(i) threats or hazards to the security or integrity of the information; and

(ii) unauthorized uses or disclosures of the information

42 U.S. Code § 1320d–2(d)(2).

Nothing in the statute, including as amended by the HITECH Act, makes a health care / non-health care distinction. Neither does the statute add an additional gloss of “detrimental to any person” as the NPRM does. The statute rather presumed *all* unauthorized uses or disclosures to be detrimental to the specific individual (and certainly not to “any” person).

As for the HIAA Regulations, “health care” is defined at 45 CFR § 160.103 and appears well over 400 times in the HIPAA Rules. By contrast, “non-health care” appears only once, as a straight-forward modifier of “professional” and in alternate form perhaps two other times²⁴ The proposed adoption of “a non-health care purpose” standard is confusing, practically alien to the HIPAA rules, and arbitrarily upsets the carefully calibrated structure of the Privacy Rule.

As catalogued below, current HIPAA rules allow disclosures that would otherwise be prohibited without a HIPAA authorization under dozens upon dozens of “non-health care” circumstances and situations, most of which do not provide any opportunity for the patient or individual to object to the disclosure:

§ 160.308(c) (to OCR for the purpose of ascertaining compliance with the applicable administrative simplification provisions)

§ 164.502(a)(2)(ii) (when required by the Secretary under subpart C of part 160 to investigate or determine the covered entity’s regulatory compliance)

§ 164.502(j)(1) ((i) a workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and (ii) The disclosure is to: A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity)

²⁴ 45 CFR § 164.501 and §§ 164.512(c)(2)(i) and (c)(3).

45 CFR § 164.510, where opportunity to object is generally required except in cases of incapacity or emergency.

§ 164.510(a)(1)(i)(A) (patient name)

§ 164.510(a)(1)(i)(B) (patient location)

§ 164.510(a)(1)(i)(D) (individual's religion)

§ 164.510(a)(1)(ii)(A) (to clergy)

§ 164.510(a)(1)(ii)(B) (to individuals)

§ 164.510(a)(3) (during emergency or incapacity)

§ 164.510(b)(4) (disaster relief)

§ 164.510(b)(5) (death)

45 CFR § 164.512, where an authorization or opportunity to object is generally not required.

§ 164.512(a) (where required by law)

§ 164.512(b) (public health activities)

§ 164.512(b)(1)(i) (reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions)

§ 164.512(b)(1)(ii) (to a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect)

§ 164.512(b)(1)(iii) (for activities related to the quality, safety or effectiveness of FDA regulated products or activities)

§ 164.512(b)(1)(iii)(A) (to collect or report adverse events (with respect to food or dietary supplements), product defects or problems (including labeling), or biological product deviations)

§ 164.512(b)(1)(iii)(B) (to track FDA-regulated products)

§ 164.512(b)(1)(iii)(C) (to enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback))

§ 164.512(b)(1)(iii)(D) (to conduct post marketing surveillance)

§ 164.512(b)(1)(iv) (to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition)

§ 164.512(b)(1)(vi) (to a school about an individual who is a student or prospective student of the school, if limited to proof of immunization required by law and agreement obtained by parent or guardian of child or of adult individual)

§ 164.512(b)(2) (if the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1))

§ 164.512(c)(1)(i) (about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence (other than child abuse covered above) to a government authority, including a social service or protective services agency, authorized by law to receive such reports) to the extent the disclosure is required law)

§ 164.512(c)(1)(iii)(A) (abuse, neglect, or domestic violence reporting to the extent authorized by statute or regulation and necessary to prevent serious harm to the individual or other potential victims)

§ 164.512(c)(1)(iii)(B) (abuse, neglect, or domestic violence reporting to the extent authorized by statute or regulation in certain cases of incapacity of individual)

§ 164.512(d)(1) (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)

§ 164.512(d)(1) (i), (iii), and (iv) (with exceptions, activities necessary for appropriate oversight of (i) the health care system; (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance)

§ 164.512(d)(3) (an oversight activity or investigation relating to a claim for public benefits not related to health).

§ 164.512(e)(1)(i) (in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order)

§ 164.512(e)(1)(ii) (in the course of any judicial or administrative proceeding in response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal)

§ 164.512(f)(1) (as required by law including laws that require the reporting of certain types of wounds or other physical injuries (except child abuse, or child neglect, or abuse, neglect, or domestic violence))

§ 164.512(f)(1)(ii)(A) (in compliance with and as limited by the relevant requirements of a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer)

§ 164.512(f)(1)(ii)(B) (a grand jury subpoena)

§ 164.512(f)(1)(ii)(C) (an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law,

provided that: (1) The information sought is relevant and material to a legitimate law enforcement inquiry; (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) De-identified information could not reasonably be used)

§ 164.512(f)(1)(ii)(C)(2) (name and address; date and place of birth; Social security number; ABO blood type and rh factor; type of injury; date and time of treatment; date and time of death; a description of distinguishing physical characteristics—in response to a law enforcement official's request for information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person)

§ 164.512(f)(3) (in response to a law enforcement official's request for information about an individual who is or is suspected to be a victim of a crime, in certain cases of incapacity)

§ 164.512(f)(4) (to a law enforcement official for the purpose of alerting law enforcement of the death of an individual if the covered entity has a suspicion that such death may have resulted from criminal conduct)

§ 164.512(f)(5) (information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity)

§ 164.512(f)(6) (reporting crimes (except for abuse) to law enforcement in offsite emergencies)

§ 164.512(g)(1) (to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law)

§ 164.512(g)(2) (to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent)

§ 164.512(h) (to organ procurement organizations or other entities engaged in the procurement, banking or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating donation and transplantation)

§ 164.512(i)(1)(i) (for certain IRB or privacy board approved research purposes)

§ 164.512(i)(1)(ii) (as necessary to prepare a research protocol or for similar purposes preparatory to research)

§ 164.512(i)(1)(iii) (for research on the protected health information of decedents)

§ 164.512(j)(1)(i) (if the covered entity, in good faith, believes the use or disclosure: (A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) Is to a person or persons reasonably able to prevent or lessen the threat)

§ 164.512(j)(1)(ii) (if the covered entity, in good faith, believes the use or disclosure: Is necessary for law enforcement authorities to identify or apprehend an individual: (A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or (B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody)

§ 164.512(k)(1)(i) (of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission)

§ 164.512(k)(1)(ii) (for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs)

§ 164.512(k)(1)(iii) (to determine eligibility for or entitlement to benefits under the laws administered by the Secretary of Veterans Affairs)

§ 164.512(k)(1)(iv) (of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel)

§ 164.512(k)(2) (to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act)

§ 164.512(k)(3) (for the provision of protective services to the President or to foreign heads of state)

§ 164.512(k)(4) (to make medical suitability determinations in the Department of State for security clearances among other State Department reasons)

§ 164.512(k)(5) (information about prisoners or those held in custody to correctional institutions)

§ 164.512(k)(6) (by covered entities that are government programs providing public benefits for coordination purposes)

§ 164.512(l) (to the extent necessary to comply with laws relating to workers' compensation or other similar programs)

§ 164.514(f) (for certain fundraising purposes and communications)

With such an enormous number of "non-health care" related permitted disclosures, it is arbitrary and capricious to base the NPRM on a purported desire "to avoid the circumstance where an existing provision of the Privacy Rule is used to request . . . PHI related to reproductive health care for a non-health care purpose." HIPAA does not give free reign for covered entities to disclose protected health information so long as there is a "health care purpose." Rather, maximal freedom is given to communication of information related to the *direct* treatment of a patient (and to those involved in the treatment), with stricter conditions for disclosures of PHI related to payment and operations. See 45 CFR §§ 164.502(a)(1)(ii) and (b)(2)(i) and § 164.506(c). Beyond those patient-tailored permissions, the ability to make other "health care" related disclosures is typically regulated much the same way as the multiple dozens of "non-health care related" permitted disclosures.

The Departments proposed use of health care and non-health care purposes is incompatible with the structure of the HIPAA rules and not supported by HIPAA's statutory scheme.

Conclusion

The Department claims that “after *Dobbs*, the Department has heard concerns that civil, criminal, or administrative investigations or proceedings have been instituted or threatened on the basis of reproductive health care that is lawful under the circumstances in which it is provided.”²⁵ “Hearing concerns” is not evidence and is even farther from the substantiation necessary to withstand APA scrutiny. The most likely explanation for the lack of the requisite evidence is that it simply does not exist. Experience from over the last 20 years has proven that HIPAA struck the right balance on the sensitive questions of balancing public interest and privacy in health care delivery. If the Department seeks to continue a campaign of resistance to the *Dobbs* decision, it must somewhere other than HIPAA.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger Severino". The signature is fluid and cursive, with a long horizontal stroke at the end.

Roger Severino

²⁵ 73 FR 23507.