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*Via Federal eRulemaking Portal*

The Honorable Xavier Becerra  
Secretary, U.S. Department of Health and Human Services  
Melanie Fontes Rainer  
Director, Office for Civil Rights  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

RE: HIPAA and Reproductive Health Care Privacy NPRM (RIN 0945-AA20)

Dear Secretary Becerra and Director Fontes Rainer:

The undersigned State Attorneys General of Arizona, California, Colorado, Connecticut, Delaware, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New York, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, Wisconsin, and Washington D.C. (“the States”) write in response to the Notice of Proposed Rulemaking (“NPRM”) issued by the U.S. Department of Health and Human Services’s (“HHS” or “Department”) Office for Civil Rights (“OCR”) entitled “HIPAA Privacy Rule to Support Reproductive Health Care Privacy,” which proposes to revise the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”), issued pursuant to section 264 of the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

The States commend the Department’s efforts to safeguard reproductive health care privacy through the proposed amendments to the HIPAA Privacy Rule (“Proposed Rule”). As stated in the States’ March 27, 2023 letter to Secretary Becerra calling for the Department to take “swift action to safeguard the privacy of sensitive reproductive health care data by initiating rulemaking to close gaps in the HIPAA Privacy Rule,” the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization* has created a climate of uncertainty and fear in the provision of reproductive health care throughout the country.<sup>1</sup> At the same time, rapid technological advances have transformed how health care providers and individuals collect and store their personal health information, including reproductive health data. Existing privacy

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<sup>1</sup> No. 19-1392, 597 U.S. \_\_\_\_ (2022).

protections have not kept up with these changes and fail to contemplate circumstances in which basic health care is subject to civil liability and criminal penalties.

For the reasons set forth below, the signatory States strongly support the additional protections offered by the Proposed Rule, and urge the Department to move expeditiously to issue it and apply the standard compliance date of 180 days after the effective date of the final rule. The Department’s proposed modifications would help to ensure that private health information is not used against people for seeking, obtaining, providing, or facilitating lawful reproductive health care, and would give individuals confidence that their protected health information (“PHI”) will be kept private. Drawing on common experiences among the States, we also address several specific points on which HHS has requested comment, and offer recommendations to further strengthen the protections contained in the Proposed Rule.<sup>2</sup>

### **I. A Drastically-Shifting Legal Landscape Necessitates More Robust Privacy Protections for Reproductive Care**

Last summer, the Supreme Court overturned *Roe v. Wade* and *Planned Parenthood v. Casey* in its *Dobbs* decision, holding that the United States Constitution does not guarantee a right to abortion. The Court thereby erased almost 50 years of precedent and created significant uncertainty in the state of the law surrounding the provision of reproductive health care. The ruling has placed everyone involved in assisting, providing, and obtaining such care at risk of investigation, civil liability, and criminal prosecution.<sup>3</sup>

*Dobbs* empowered each state to decide whether and to what degree to ban or restrict abortion.<sup>4</sup> Patients and providers thus immediately confronted a tangled web of bans and restrictions. Fifteen states currently have laws in effect prohibiting abortion under all or most circumstances. Such state laws include pre-*Roe* abortion bans, so-called “trigger laws” that promised to ban abortion if and when *Roe* was overturned, and other restrictions that courts had previously enjoined for violating *Roe*’s constitutional floor.<sup>5</sup> In some cases, individual states have multiple, conflicting abortion laws on the books. As a Senate report noted in August 2022, “[i]n just one example of the confusion facing women right now, Kentucky has three separate statutes with three separate timelines for when abortion is legal: one law has gone into effect, while two others are blocked by a court and await further judicial review.”<sup>6</sup> Other states such as Texas and Oklahoma passed vigilante laws creating civil liability for “aiding and abetting” those

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<sup>2</sup> 88 Fed. Reg. 23551 (Apr. 17, 2023).

<sup>3</sup> Health care providers found to have provided prohibited care also face potential professional censure, including the loss of their medical licenses. NPR: Morning Edition, *Doctors Who Would Like to Defy Abortion Laws Say It’s Too Risky*, NPR (Nov. 22, 2022), <https://www.npr.org/2022/11/22/1138558392/doctors-who-would-like-to-defy-abortion-laws-say-its-too-risky>.

<sup>4</sup> *Dobbs*, 597 U.S. \_\_\_ (Kavanaugh, J., concurring).

<sup>5</sup> Elizabeth Nash and Isabel Guarnieri, *13 States Have Abortion Trigger Bans—Here’s What Happens When Roe is Overturned*, GUTTMACHER INSTITUTE (June 6, 2022), <https://www.guttmacher.org/article/2022/06/13-states-have-abortion-trigger-bans-heres-what-happens-when-roe-is-overturned>.

<sup>6</sup> DEMOCRATIC STAFF OF S. COMM. ON HEALTH, EDUC., LAB., & PENSIONS, REP. ON IMPACTS OF A POST-*ROE* AMERICA: THE STATE OF ABORTION POLICY AFTER *DOBBS*, 2 (Aug. 1, 2022), <https://www.help.senate.gov/imo/media/doc/8.01.2022%20Final%20Post-Dobbs%20Report.pdf> (internal citations omitted).

seeking abortion.<sup>7</sup> And, in recent weeks, Idaho became the first state to enact an “abortion trafficking” law aimed at restricting residents’ ability to travel out-of-state to obtain care.<sup>8</sup>

Abortion opponents, however, have not been content to stop at state-level restrictions. In November 2022, anti-abortion groups filed a federal lawsuit in Amarillo, Texas seeking to overturn the FDA’s longstanding approval of mifepristone as part of the two-drug regimen for medication abortion.<sup>9</sup> But for intervention from the Supreme Court, the District Court and Court of Appeals would have imposed a nationwide preliminary injunction eliminating or severely restricting access to medication abortion.<sup>10</sup> Anti-abortion groups and states have also successfully blocked the Department from protecting access to reproductive health care under federal law. They obtained an injunction within the State of Texas that bars the enforcement of the Department’s Emergency Medical Treatment & Labor Act guidance requiring physicians to provide emergency abortion care to preserve the health of the pregnant person regardless of state law,<sup>11</sup> and won a judgment striking down the federal rule prohibiting the requirement of parental consent for minors seeking Title X-funded family planning services.<sup>12</sup>

The hostile and fragmented reproductive health care landscape heavily burdens patients in need of health care. Reports continue to emerge—even in states with abortion bans that include exceptions for the health or life of the pregnant person—of patients with serious pregnancy complications being denied care or forced to wait until they are “sick enough,” and often enduring unnecessary pain and life-threatening complications, to justify pregnancy termination.<sup>13</sup> The same confusion hangs over survivors of rape and incest attempting to access abortion care.<sup>14</sup> Providers also reportedly have denied or delayed crucial miscarriage care<sup>15</sup> and health care that might have an incidental effect on a person’s reproductive capacity or pregnancy, like chemotherapy for cancer or the prescription of certain drugs to treat autoimmune diseases

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<sup>7</sup> See, e.g., Tex. S.B. 8 (codified at TEX. HEALTH & SAFETY CODE ANN. § 171.208 (West 2021)); Okla. H.B. 4327 (codified at OKLA. STAT. ANN. tit. 63, § 1-745.55 (West 2022)).

<sup>8</sup> 2023 Idaho H.B. 242 (codified at IDAHO CODE ANN. § 18-623 (West 2023)).

<sup>9</sup> Brendan Pierson, *Anti-Abortion Groups Ask U.S. Court to Pull Approval for Abortion Drugs*, REUTERS (Nov. 18, 2022, 4:46 PM), <https://www.reuters.com/legal/anti-abortion-groups-ask-us-court-pull-approval-abortion-drugs-2022-11-18/>.

<sup>10</sup> See *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023), *stay granted in part* by No. 23-10362 (5th Cir. Apr. 12, 2023) and *stay granted sub nom. Danco Lab’ys, LLC v. All. for Hippocratic Med.*, No. 22A901 (U.S. Apr. 21, 2023).

<sup>11</sup> *Texas v. Becerra*, No. 5:22-cv-185-H (N.D. Tex. Aug. 23, 2022), *judgment entered*, No. 5:22-cv-185-H (N.D. Tex. Jan. 13, 2023), and *appeal dismissed*, No. 22-11037 (5th Cir. Jan. 26, 2023).

<sup>12</sup> *Deanda v. Becerra*, No. 2:20-cv-092-Z (N.D. Tex. Dec. 8, 2022), *judgment entered*, No. 2:20-cv-092-Z (N.D. Tex. Dec. 20, 2022).

<sup>13</sup> See Jessica Valenti, *I Write About Post-Roe America Every Day. It’s Worse than You Think.*, N.Y. Times (Nov. 5, 2022), <https://www.nytimes.com/2022/11/05/opinion/election-abortion-roe-women.html>; Devon Minnick et al., *Disorder in the Post-Roe World? . . . ‘It is So Ordered’ by the Dobbs Court*, HEALTH LAW WKLY. (Aug. 19, 2022), [https://www.americanhealthlaw.org/content-library/health-law-weekly/article/50b326b2-e6ee-45e1-89e3-cab572f818c6/disorder-in-the-post-roe-world-it-is-so-ordered-by#\\_ednref9](https://www.americanhealthlaw.org/content-library/health-law-weekly/article/50b326b2-e6ee-45e1-89e3-cab572f818c6/disorder-in-the-post-roe-world-it-is-so-ordered-by#_ednref9) (citing Lauren Coleman-Lochner et al., *Doctors Fearing Legal Blowback Are Denying Life-Saving Abortions*, BLOOMBERG LAW (July 12, 2022), <https://news.bloomberglaw.com/health-law-and-business/doctors-fearing-legal-blowback-are-denying-life-saving-abortions>).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

like rheumatoid arthritis,<sup>16</sup> because of the uncertainty created by vague and overbroad state abortion bans. Even fertility care and common forms of contraception are potentially at risk given state “fetal personhood” statutes.<sup>17</sup>

These risks are most pronounced for historically underserved populations, including low-income people and people of color. Maternal and infant health outcomes are worse for these groups, with Black people dying from pregnancy-related causes at three times the rate of white people.<sup>18</sup> Low-income people and people of color have long been disproportionately investigated by criminal and family regulation authorities for their pregnancy outcomes, including following a miscarriage or stillbirth.<sup>19</sup> Such investigations were common even before *Roe* was overturned, with women of color and Black women in particular being by far the most likely to be impacted.<sup>20</sup> The disclosure of information regarding pregnant patients’ drug use or history of substance use disorder treatment may subject them to criminal or child services investigation, or, in some states, cause them to be involuntarily committed to a treatment facility.<sup>21</sup> These risks discourage pregnant people from utilizing health care and endanger the patient-provider relationship, even in states that are not hostile to abortion rights.<sup>22</sup> For example, in the cases of Adora Perez and Chelsea Becker, district attorneys misapplied the California Penal Code provisions governing murder that were intended to protect pregnant women from third-party harm resulting in the death of the fetus to criminalize the pregnant people for their pregnancy losses, based on information suggesting that they had used drugs during their pregnancies.<sup>23</sup>

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<sup>16</sup> Celine Castronuovo, *Many Female Arthritis Drug Users Face Restrictions After Dobbs*, BLOOMBERG LAW (Nov. 14, 2022, 5:25 AM), <https://news.bloomberglaw.com/health-law-and-business/many-female-arthritis-drug-users-face-restrictions-after-dobbs>.

<sup>17</sup> Grace Panetta, “*This is Our New Normal*”: Fertility Treatment Advocates Are Gearing Up to Fight Abortion Bans and Personhood Laws, 19TH NEWS (Nov. 14, 2022, 8:30 PM), <https://19thnews.org/2022/11/resolve-infertility-advocates-abortion-bans-laws/>; PREGNANCY JUSTICE, WHEN FETUSES GAIN PERSONHOOD: UNDERSTANDING THE IMPACT ON IVF, CONTRACEPTION, MEDICAL TREATMENT, CRIMINAL LAW, CHILD SUPPORT, AND BEYOND (Aug. 17, 2022), <https://www.pregnancyjusticeus.org/wp-content/uploads/2022/12/fetal-personhood-with-appendix-UPDATED-1.pdf>.

<sup>18</sup> Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Nov. 1, 2022), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/>; *Working Together to Reduce Black Maternal Mortality*, CTRS. FOR DISEASE CTRL. & PREVENTION (“CDC”) (April 3, 2023), <https://www.cdc.gov/healthequity/features/maternal-mortality/index.html>.

<sup>19</sup> Yoonji Han, *Black Women Are Twice as Likely to Have Stillbirths. With Roe Overturned, Experts Say More Women of Color Could be Investigated For Miscarriages*, INSIDER (Jul. 1, 2022, 3:57 PM), <https://www.insider.com/roe-wade-dobbs-abortion-miscarriage-pregnancy-manslaughter-charges-race-2022-6>.

<sup>20</sup> See *id.* (citing Lynn M. Paltrow and Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973-2005: Implications for Women’s Legal Status and Public Health*, 38 J. OF HEALTH POL. AND LAW 299 (2013)).

<sup>21</sup> See AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, COMM. OP. NO. 473, SUBSTANCE ABUSE REPORTING AND PREGNANCY: THE ROLE OF THE OBSTETRICIAN-GYNECOLOGIST (Jan. 2011, reaffirmed 2014), <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2011/01/substance-abuse-reporting-and-pregnancy.pdf>.

<sup>22</sup> PREGNANCY JUSTICE, CONFRONTING PREGNANCY CRIMINALIZATION 7, 11 (July 2022), <https://www.pregnancyjusticeus.org/wp-content/uploads/2022/12/202211-PJ-Toolkit-Update-2.pdf>.

<sup>23</sup> See Nigel Duara, *Meth, a Mother, and a Stillbirth: Imprisoned Mom Wants Her ‘Manslaughter’ Case Reopened*, CAL MATTERS (May 10, 2022), <https://calmatters.org/justice/criminal-justice/2022/02/stillbirth-prison-manslaughter/>.

Given this rapidly-changing backdrop of extreme legal risks and increasing uncertainty, it is critical that additional guardrails be added to the Privacy Rule to protect against the disclosure of reproductive health information, and that pregnant people be made fully aware of the ways in which their PHI may be used and disclosed to third-parties that are not covered entities.<sup>24</sup> The States therefore enthusiastically support the Department’s efforts to revise the Privacy Rule to ameliorate the new risks to privacy, patient trust, and health care quality.<sup>25</sup>

The Privacy Rule should also be updated in light of the heightened potential for the surveillance of health care decisions with the digitization of patients’ health care information. As people in abortion ban states increasingly turn to the internet for basic health care information, law enforcement will continue to seek the disclosure of sensitive data that is stored and transmitted online. Software programs, cloud-based systems, and mobile health and fitness apps routinely collect health information from users that is not covered under the current HIPAA Privacy Rule, which applies only to covered entities (and their business associates) and not the many third-parties that now hold sensitive health data.<sup>26</sup> Moreover, new regulations aimed at promoting the sharing of electronic health information<sup>27</sup> will make patient records relating to abortion care even more readily available in states that criminalize such care. These developments underscore the need to adopt the Proposed Rule. The States applaud the Department for taking action while recognizing the need for more to be done to protect data privacy nationwide.<sup>28</sup>

## **II. The States’ Recent Efforts to Protect Reproductive Health Privacy**

Following the Supreme Court’s decision in *Dobbs*, many signatory States have taken additional steps to protect the reproductive health privacy of their residents. California, for example, has enacted the following:

- Assembly Bill 2091, which protects abortion records in California from access by out-of-state law enforcement agencies and other third-parties;
- Assembly Bill 1242, which ensures that law enforcement and the tech industry do not cooperate with other states’ efforts to criminalize abortion care;

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<sup>24</sup> See *infra* Section VII.

<sup>25</sup> 88 Fed. Reg. 23521.

<sup>26</sup> See Michael H. Hinckle et al., *US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part I: HIPPA*, 11 NAT’L L. REV. (Oct. 18, 2021), <https://www.natlawreview.com/article/us-regulatory-considerations-applicable-to-digital-health-providers-and-suppliers>; CTR. FOR DEMOCRACY & TECH., PROPOSED CONSUMER PRIVACY FRAMEWORK FOR HEALTH DATA 4 (Feb. 2021), <https://cdt.org/wp-content/uploads/2021/02/2021-02-09-CDT-and-eHI-Proposed-Consumer-Privacy-Framework-for-Health-Data-d-FINAL.pdf>.

<sup>27</sup> See 88 Fed. Reg. 23746 (April 18, 2023).

<sup>28</sup> The Department acknowledges that there are wide swaths of sensitive health information not protected by the Privacy Rule, such as information stored on a personal device. 88 Fed. Reg. 23538. Other agencies, such as the FTC, must also act swiftly. In addition, the exigencies of the current climate dictate a more global approach to data privacy.



- Assembly Bill 2223, which bolsters the state’s Reproductive Privacy Act, ensuring that no one in California will be investigated, prosecuted or incarcerated for ending their pregnancy or experiencing pregnancy loss;<sup>29</sup>
- Assembly Bill 1666, which bars enforcement of out-of-state civil anti-abortion actions against anyone who receives or seeks, performs or induces, or aids someone in obtaining an abortion; and
- Executive Order N-12-22, which prohibits California state agencies and departments from cooperating with out-of-state agencies to extradite anyone seeking, providing, or assisting with access to reproductive health care services, including abortion, in California. The Executive Order also prohibits state agencies from sharing information in connection with proceedings by out-of-state actors to prosecute individuals for the provision of reproductive health care services.

As part of a comprehensive package of reproductive health care protections, New York has enacted:

- S.9077A/A.10372A, which prohibits state and local law enforcement from cooperating with, or providing information to, an out-of-state agency regarding a lawful abortion in the state;<sup>30</sup>
- S.9384A/A.9818A, which protects patients and reproductive health care service providers by ensuring that they can keep their addresses confidential;<sup>31</sup>
- Further protections against the collection of reproductive health information and geofencing for advertising purposes.<sup>32</sup>

Washington enacted the “My Health, My Data Act,” which increases consumer protections around collecting, sharing and selling consumer health data, including data collected by apps, websites, and organizations.<sup>33</sup> Connecticut passed “An Act Concerning Online Privacy, Data and Safety Protections” into law, which regulates the collection, use, sharing, and sale of personal health data and prohibits geofencing around health care facilities.<sup>34</sup> Massachusetts enacted comprehensive reproductive health protections in 2022 including:

- Mass. Gen. Laws ch. 127, § 20, which prohibits state and local law enforcement from providing information or assistance to a federal or out-of-state law enforcement agency,

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<sup>29</sup> See Cal. Health & Safety Code § 123460 et seq.

<sup>30</sup> See N.Y. Exec. Law § 837-w (McKinney).

<sup>31</sup> See N.Y. Exec. Law § 108 (McKinney).

<sup>32</sup> Press Release, Governor Kathy Hochul’s Press Office, Governor Hochul Announces Major Actions to Strengthen Abortion Protections and Access as Part of FY 2024 Budget, (May 3, 2023), <https://www.governor.ny.gov/news/governor-hochul-announces-major-actions-strengthen-abortion-protections-and-access-part-fy> (“To safeguard personal data, the budget enacts protections that would prevent companies headquartered or incorporated in New York State from sharing information out-of-state law enforcement who conduct investigations into abortion procedures that are legal in New York State. Corporations and associations are also prevented from delivering by electronic means any digital advertisement to a user through the use of geofencing at any health care facility.”).

<sup>33</sup> H.B. 1155, “My Health, My Data Act,” 68th Leg., Reg. Sess. (Wash. 2023) (codified at WASH. REV. CODE §44.28 and Tit. 19).

<sup>34</sup> An Act Concerning Online Privacy, Data and Safety Protections. S.B. No. 3, 2023 Leg., Reg. Sess. (Conn. 2023).

or a private citizen or quasi-law enforcement agent, concerning reproductive health care that would be legal if provided within Massachusetts;

- Mass. Gen. Laws ch. 127, §§ 33–36, which prohibits litigation activity in Massachusetts in connection with an out-of-state litigation over reproductive health care activity;
- Mass. Gen. Laws ch. 127, §§ 38–40, which prohibits extradition for reproductive health-related crimes.

Other states have enacted shield laws and prohibitions against extradition<sup>35</sup> in addition to guarantees of confidentiality for patients and providers.<sup>36</sup>

Through these efforts, the signatory States have learned critical lessons that inform the recommendations set forth below.

### **III. Recommendations to Further Strengthen and Clarify the Definitions in Section 160.103**

#### **a. A Broad Definition of “Reproductive Health” Is Warranted**

The States welcome the Department’s decision to add a new definition of “reproductive health care” as a subcategory of the existing defined term “health care.” But the States urge the

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<sup>35</sup> See, e.g., S.B. 23-188, 74th Gen. Assemb., Reg. Sess. (Colo. 2023) (codified at COLO. REV. STAT. § 12-30-121 et. seq. (2023) (prohibiting state resources from being used to comply with out-of-state investigations and actions arising from the provision of legal reproductive health care); S.H.B. 5414, 2022 Leg., Reg. Sess. (Conn. 2022) (codified at 2022 Conn. Pub. Act No 22-19) (prohibiting the issuance of foreign summons in cases arising from the provision or receipt of, or assistance in obtaining, reproductive health care, and barring extradition); H.B. 4664, 103rd Gen. Assemb., Reg. Sess. (Ill. 2023) (codified at 2023 Ill. Legis. Serv. P.A. 102-1117) (limiting the issuance of subpoenas related to lawful health care activity and prohibiting extradition); S.B. 859, 445th Leg., Reg. Sess. (Md. 2023) (codified at 2023 Md. Legis. Serv. Ch. 247 (West)) (protecting against out-of-state investigations and legal actions); Minn. Exec. Ord. No. 22-16, “Protecting Access to Reproductive Health Care Services in Minnesota” (June 25, 2022) (same, also protecting against extradition); A.B. 3975, 220th Leg., 1st Ann. Sess. (N.J. 2022) (codified at 2022 N.J. Laws, Ch. 51) (prohibiting cooperation with out-of-state investigations by state entities); A.B. 3974, 220th Leg., 1st Ann. Sess. (N.J. 2022) (codified at 2022 N.J. Laws, Ch. 50) (shielding those charged in actions arising from abortions lawfully provided in the state from extradition); Nev. Exec. Ord. No. 2022-08 (Jun. 28, 2022) (prohibiting executive branch cooperation with out-of-state investigations and actions, and extradition, absent court order); R.I. Exec. Ord., No. 22-28 (Jul. 5, 2022) (barring executive agencies and employees from cooperating with out-of-state investigations and proceedings, and propounding a policy of declining to extradite); H.B. 89, 77th Gen. Assemb., Reg. Sess. (Vt. 2023) (codified at 2023 Vt. Acts & Resolves No. 14); S.B. 37, 77th Gen. Assemb., Reg. Sess. (Vt. 2023) (codified at 2023 Vt. Acts & Resolves No. 15) (barring public agencies and employees from providing information or resources to further an out-of-state investigation or proceeding); H.B. 1469, 68th Leg., Reg. Sess. (Wash. 2023) (codified at WASH. REV. CODE, §§ 5.51.020, 5.56.010, 9.73.040, 9.73.260, 10.55.020, 10.88.250, 10.88.320, 10.88.330, 10.96.020, 10.96.040, and 40.24.030) (shields abortion and gender-affirming care patients and providers from prosecution by out-of-state authorities and prevents cooperation with investigations); H.B. 1340, 68th Leg., Reg. Sess. (Wash. 2023) (codified at WASH. REV. CODE §§ 18.130.055, 18.130.180, § 18.130) (protects health care providers in Washington from disciplinary action for providing legal abortion and gender-affirming care in Washington); Governor Jay Inslee, Directive No. 22-12 (Wash. Jun. 30, 2022) (directing state police not to cooperate with out-of-state investigations regarding lawful abortion care).

<sup>36</sup> See H.B. 812, 445th Leg. Reg. Sess. (Md. 2023) (protecting from disclosure information related to the receipt of certain reproductive health services); H.B. 89, 77th Gen. Assemb., Reg. Sess. (Vt. 2023) (codified at 2023 Vt. Acts & Resolves No. 14) (enabling a person providing, assisting another person, or obtaining reproductive health care services to participate in an address confidentiality program).

Department to consider providing a separate definition of “reproductive health.” Including this defined term would signal that most covered entities—rather than only providers of gynecological or fertility-related care—would be required to implement changes in order to be in compliance.<sup>37</sup> The most comprehensive and coherent definition of reproductive health is the one endorsed by the International Conference on Population and Development in Cairo in 1994 and subsequently adopted by the United Nations<sup>38</sup> and the World Health Organization:

Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so.<sup>39</sup>

This definition has the benefit of global backing and reinforces the legitimacy of discussing health against the language of rights and access. It further recognizes that, in terms of sexuality and reproduction, the needs of people go well beyond fertility and pregnancy, and provides a non-judgmental and inclusive framework regarding sexual identity, sexual activity, and family-planning. Thus, we urge the Department to include in this rulemaking an appropriately expansive, scientifically-sound, and functional definition of “reproductive health” to avoid any possible ambiguities concerning what type of health care may be covered by the Proposed Rule.

#### **b. The States Recommend the Final Rule Incorporate Examples of “Reproductive Health Care” into the Regulatory Text**

The States support the Department’s proposal to define “reproductive health care” but suggest that it include additional examples in the preamble as well as a specific, non-exhaustive list of examples of reproductive health care in the regulatory text in order to clarify the Department’s intent. It is well-established that preamble language operates as guidance and provides the agency’s contemporaneous interpretation and explanation of the regulatory

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<sup>37</sup> While several federal agencies appear to use functional definitions of “reproductive health,” many of these definitions fall short, and in some cases incorporate outdated and exclusionary terminology. For example, the National Institutes of Health defines reproductive health as “the condition of female and male reproductive systems during all life stages,” and explains that these systems are made up of both reproductive organs and hormone-producing glands elsewhere in the body. NAT’L INSTS. OF HEALTH, NAT’L INST. OF ENV’T HEALTH SCI., REPRODUCTIVE HEALTH IN FEMALES AND MALES (Feb. 2020), [https://www.niehs.nih.gov/health/materials/reproductive\\_health\\_in\\_females\\_and\\_males\\_508.pdf](https://www.niehs.nih.gov/health/materials/reproductive_health_in_females_and_males_508.pdf).

Similarly, the CDC’s Division of Reproductive Health describes the term with a focus on male and female reproductive and maternal health, and infant health issues. CDC Div. of Reprod. Health, *About Us*, CDC (April 20, 2022), <https://www.cdc.gov/reproductivehealth/drh/about-us/index.htm>. These definitions have the potential to exclude the reproductive health concerns of trans and gender-expansive people.

<sup>38</sup> Press Release, Department for Economic and Social Information Policy Analysis, *Reproductive Rights and Reproductive Health: A Concise Report*, U.N. Press Release POP/623, (Sept. 25, 1996), <https://press.un.org/en/1996/19960925.pop623.html>.

<sup>39</sup> UNITED NATIONS, REPORT ON THE INTERNATIONAL CONFERENCE ON POPULATION AND DEVELOPMENT 40 (Sept. 1994), [https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/icpd\\_en.pdf](https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/icpd_en.pdf).



requirements. Examples in the regulatory text may lay to rest groundless attempts to cabin what constitutes “reproductive health care.”

In particular, examples would help to clarify the Department’s intent to expand the definition to include “care, services and supplies” even when unrelated to pregnancy or when provided beyond reproductive age. As currently written, the definition of “reproductive health care” could exclude gender-affirming care and assisted reproduction. In particular, the States urge the Department to name sexual health services such as STI screening and treatment, including pre-exposure prophylaxis (PrEP) and vaccinations for HPV and other sexually transmitted infections, as well as diagnosis and treatment relating to the endocrine system, including hormone therapies and other forms of gender-affirming care as part of “reproductive health care.” Moreover, the States urge the Department to select examples illustrating that reproductive health care, services and supplies cut across a variety of needs beyond contraception, abortion, and prenatal care, and include infertility and gender-affirming treatment. *See infra* Section IV.

While it would be impractical if not impossible for OCR to provide an exhaustive list of all reproductive health care or services, providing some such examples may relieve the burdens on health care providers. Further, specific examples will ensure that, should a regulated entity receive a subpoena for reproductive PHI, the regulated entity knows what information cannot be disclosed in response to the subpoena per the Proposed Rule.

### **c. The Department Should Clarify the Meanings of “Birth” and “Death”**

The States support the as-proposed revised definition of “person,” which corresponds with established federal law and does not include a fertilized egg, embryo, or fetus. The need for this clarification has been underscored by the inflammatory and legally inaccurate language—such as the term “unborn human”—that has been propounded in recent state legislation and court decisions concerning reproductive issues.<sup>40</sup> While this clarified definition of “person” and the new definition of “public health” assist in setting a baseline understanding of “birth” and “death,” we would nonetheless urge the Department to go further and define “birth” and “death” terms separately to clarify that termination of pregnancy is not a public health reporting event, and therefore is not subject to reporting requirements, under the Privacy Rule.

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<sup>40</sup> *See All. for Hippocratic Med.*, 2023 WL 2825871, at \*14 (discussing the potential for injury to unborn humans); H.B. 481, 2019 Gen. Assemb., Reg. Sess., “Living Infants Fairness and Equality Act” (Ga. 2019), (codified at GA CODE ANN. § 16-12-141 (2020) (providing “that natural persons include an unborn child”); MO. REV. STAT. § 188.026.2(2) (recognizing “that the life of each human being begins at conception and that unborn children have protectable interests in life, health, and wellbeing”). *See also* PREGNANCY JUSTICE, WHEN FETUSES GAIN PERSONHOOD at Appendix (listing state personhood provisions).

#### **IV. Recommendations to Further Strengthen Provisions on Permitted Uses and Disclosures of Protected Health Information in Section 164.502**

##### **a. The Prohibition on Use of PHI Should Apply Broadly**

The Department has requested comment on whether the proposed prohibition on the dissemination of PHI should apply broadly to any health care, rather than limiting it to reproductive health care.<sup>41</sup> The States believe that patients should not be policed or criminalized for the type of health care they seek. In that vein, the recent criminalization of gender-affirming care raises similar implications for the Privacy Rule as the criminalization of reproductive care post-*Dobbs*. Gender affirming care often involves treatment that can affect reproduction (e.g., hormone therapy and menstrual suppression) and many of the same clinics that provide abortion also provide gender affirming care and would presumably be subject to invasive requests for PHI. Clinics that provide gender-affirming services in the States draw many out-of-state patients, raising the same concerns that law enforcement from anti-trans states may go after patients and providers in the States for obtaining or providing lawful care. The States anticipate that covered entities could receive similar requests for PHI related to substance use disorder, sexually transmitted infection and fertility treatment. Because of these significant concerns, the States suggest the Department include a definition of “reproductive health” and examples of “reproductive health care.” *See supra* Section III. We urge the Department to consider broadening the scope of this Rule to other forms of health care.

##### **b. The States Recommend Reevaluating the “Primarily for the Purpose of” Language in the Rule of Construction**

The States enthusiastically support the Department’s proposal to prohibit the use or disclosure of PHI for the purpose of investigating or imposing liability on persons seeking, obtaining, providing, or facilitating reproductive health care. The States have concerns, however, about the Rule of Construction, which expressly permits the use or disclosure of PHI “unless such use or disclosure is *primarily for the purpose of* investigating or imposing liability on any person for the mere act of seeking, obtaining, providing or facilitating reproductive health care.”<sup>42</sup> There is a risk that the “primarily for the purpose” language could be exploited to manufacture a “primary” and permissible purpose as a pretext in order to permit PHI to be used or disclosed for a prohibited purpose. For example, a state licensing agency could request reproductive health data purportedly and “primarily” for quality of care oversight, but in fact use that information to investigate patients of the licensees even though they are receiving lawful health care. Or, as the Proposed Rule is currently written, a law enforcement agency could request reproductive health data for the primary purpose of investigating purported financial crimes by a provider of reproductive health care services while nonetheless acknowledging a secondary purpose of investigating the provision of abortion care.

Dropping the word “primarily” would address this issue without interfering with the intent of the Rule of Construction. “Primarily” is not an essential word—and the Department’s discussion of the Rule of Construction would be unchanged—because “the mere act” language

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<sup>41</sup> 88 Fed. Reg. 23534.

<sup>42</sup> 88 Fed. Reg. 23532-33 [proposed 45 CFR 164.502(a)(5)(iii)(D)] (emphasis supplied).

achieves the intent of the Rule; without “primarily,” the prohibition would still pertain to the “mere act” of “seeking, obtaining, providing, or facilitating reproductive health care.” Therefore, omitting “primarily” would clarify the Department’s objectives and continue to allow the acquisition of PHI for permissible purposes. The health oversight activities discussed in the NPRM, for example, would still be permitted because the health oversight agencies would not be seeking PHI for the “mere act” of “seeking, obtaining, providing, or facilitating reproductive health care,” but instead they would be seeking PHI to assess, for example, unlawful billing practices.<sup>43</sup> As another example, seeking PHI in a medical negligence or professional disciplinary inquiry would not be for the “mere act” of providing reproductive health care, but for the provision of health care in a manner below the standard of care.<sup>44</sup> And omitting “primarily” likewise does not affect the Department’s explanation that the Rule of Construction operates to permit a regulated entity to use or disclose PHI to defend—as opposed to investigate or impose liability on—any person in a criminal, civil, or administrative proceeding where liability could be imposed on that person for providing reproductive health care.<sup>45</sup> For these same reasons, the States believe that “primarily” is not an essential term in § 165.12(c)(3), and recommend that it be omitted from both provisions.

Eliminating the term “primarily” would set needed guardrails around permissible disclosures of PHI in order to prevent such misuse of the exception—which is particularly critical given that PHI may lose HIPAA protections entirely after disclosure. If, however, the Department decides to keep in the language, at a minimum, OCR should provide additional examples of scenarios in which a situation would and would not be considered “primarily for the purposes of” or “primarily based on” the provision of reproductive health care.

**c. The States Suggest the Final Rule Construe What is Considered “Lawful” Care Consistent With the Intent of the Rule to Protect Privacy to the Maximum Extent**

The proposed Rule of Applicability limits the prohibition on the use and disclosure of protected health information to those instances where the health care is lawful under state or federal law.<sup>46</sup> Covered entities, individuals and those seeking PHI all would benefit from more guidance on what is lawful under the Rule of Applicability. In the current climate, there is an increasing likelihood of confusion and disagreement on what constitutes legal health care. For example, the prescription of certain medications that are known to interfere with pregnancy could be lawful under a given state statute, but nonetheless subject to legal uncertainty in the continuing push to criminalize legal health care.

Because all scenarios cannot be predicted, the Department should add an express directive that, in the event of any ambiguity or unsettled law, the scope of what is considered lawful should be interpreted consistently with the intent of the rule to protect the privacy of PHI to the maximum extent possible. While such a directive merely echoes longstanding tenets of

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<sup>43</sup> 88 Fed. Reg. 23532-33.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> 88 Fed. Reg. 23549.

statutory and regulatory construction, attacks on reproductive freedoms are ever-evolving and a default interpretation is therefore both warranted and necessary.

**d. Providers Should Not Be Permitted to Ask Patients to Authorize Prohibited Disclosures**

Rather than an outright prohibition on the use and disclosure of PHI to investigate or prosecute patients, providers, and others involved in the provision of legal reproductive health care, the Department also considered allowing a patient to authorize such uses and disclosures that would otherwise fall within the ban.<sup>47</sup> The Department was wise to reject such a construction, as it is difficult to imagine a scenario in which the patient would be asked to authorize the release of reproductive health information specifically without some level of coercion. Indeed, if the person whose information is being requested is also the subject of an investigation related to the receipt of reproductive health care, such coercion is inherent simply due to pressure to cooperate with law enforcement. Requiring authorizations from patients would moreover irredeemably erode the relationship between health care providers and their patients in a manner antithetical to the purposes of the Privacy Rule. In addition, shifting the burden of obtaining information for law enforcement or investigatory purposes onto patients—via their health care providers—inappropriately positions health care providers as tools of law enforcement agencies. Authorizing such advance waivers further raises constitutional implications relating to warrantless searches as well as the privilege against self-incrimination that are equally at odds with the purposes of the Privacy Rule.<sup>48</sup>

**e. The States Strongly Support Adherence to the Current Preemption Rule**

The States strongly endorse the Department's continued adherence to the general rule of preemption, which dictates that HIPAA preempts state laws that allow the use or disclosure of PHI about an individual's reproductive health for prohibited purposes.<sup>49</sup> State laws that provide more privacy protection, such as the laws discussed earlier in this letter, will continue to stand. As the Department recognizes, upending longstanding principles of preemption would counter Congress's intent in enacting HIPAA. If states were allowed to circumvent these privacy protections via legislation, the rule—which is essential to quality health care—would be gutted. These dangers cannot be denied. Preemption is particularly appropriate here, where the proposed Rule of Applicability currently limits the application of the regulation to those circumstances in which a state lacks any substantial interest in seeking the disclosure.<sup>50</sup>

**V. Recommendations to Ensure that Requesters and Providers Receive Adequate Guidance Relating to the Attestation Requirement in Section 164.509**

The Department proposes adding a new Attestation Requirement,<sup>51</sup> which will require covered entities to obtain an attestation that PHI is not related to the seeking of reproductive

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<sup>47</sup> 88 Fed. Reg. 23528, 23548.

<sup>48</sup> See *Ferguson v. City of Charleston*, 532 U.S. 67, 85 (2001).

<sup>49</sup> 88 Fed. Reg. 23530.

<sup>50</sup> See *id.*

<sup>51</sup> 45 C.F.R. § 164.509.

health services before releasing PHI in specific circumstances. Specifically, an attestation would be required where the person is making the request for PHI for health oversight activities authorized by law (including civil and criminal investigations and proceedings, § 164.512(d), in the course of any judicial or administrative proceeding, § 164.512(e), and for a law enforcement purpose to a law enforcement official, § 164.512(f)).

We applaud the Department’s decision to require an attestation, which is limited specifically to situations that have the greatest potential to stem from an investigation or proceeding against a person for seeking, obtaining, providing, or facilitating reproductive health care. The Department’s proposal is in line with California’s Penal Code 1524.2(c) (also known as Assembly Bill 1242) and New York’s newly enacted General Business Law § 394-f. Both laws require out-of-state law enforcement agencies seeking surveillance data or records from California and New York corporations, respectively, to provide an attestation that the investigation does not relate to providing, facilitating, or obtaining an abortion in California or, more broadly, reproductive health care services in New York, in such a manner that is legal under state law.<sup>52</sup> This issue came to prominence when Nebraska law enforcement officers charged a Nebraska woman with two felonies related to an allegedly-illegal abortion after authorities found information about the pregnancy in private messages on Meta’s Facebook Messenger.<sup>53</sup> Law enforcement obtained the messages by search warrant, although the warrant itself did not mention abortion.<sup>54</sup> While New York and California have taken the initial steps to protect people seeking reproductive health care in a post-*Dobbs* world, the Proposed Rule provides more security to those who obtain or seek to obtain lawful abortions and reproductive health care.

Modeling the Attestation Requirement after the Privacy Rule’s existing authorization requirements in 45 C.F.R. § 164.508 will ease administration for covered entities, who already regularly obtain authorizations for the release of PHI involving psychotherapy notes, for the use of PHI in marketing, and for the sale of PHI. Along the same lines, we believe a model attestation would benefit regulated entities because it would provide a baseline to begin implementing the changes in the Proposed Rule. We do not believe requiring use of the model attestation is necessary and, in fact, making the model attestation permissive rather than mandatory would allow flexibility for regulated entities who may have unique administrative requirements and processes. The Department seeks comment on what should be included in a

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<sup>52</sup> A.B. 1242, 2022 Leg., Reg. Sess. (Ca. 2022) (codified at Cal. Penal Code § 1524.2(c)(2)) (“This bill would require an out-of-state warrant for the records listed above to include an attestation that the evidence sought is not related to an investigation into, or enforcement of, a prohibited violation [defined as any violation of law that creates liability for, or arising out of providing, facilitating, or obtaining (or intending or attempting to provide, facilitate, and obtain) an abortion that is lawful under California law]. The bill would prohibit the production of records by a California corporation when the corporation knows or should know that the warrant relates to an investigation into, or enforcement of, a prohibited violation.”); N.Y. Gen. Business Law 394f (added by New York Laws 2023, ch. 57, Sec. U-1, eff. Jul. 2, 2023).

<sup>53</sup> Emily Baker-White and Sarah Emerson, *Facebook Gave Nebraska Cops a Teen’s DMs. They Used Them to Prosecute Her for Having an Abortion*, FORBES (Aug. 8, 2022, 9:23 PM), <https://www.forbes.com/sites/emilybaker-white/2022/08/08/facebook-abortion-teen-dms/?sh=74e60e91579c>.

<sup>54</sup> Andrea Vittorio, *New Law Buffers California Companies From Abortion Data Requests*, BLOOMBERG NEWS (Sept. 28, 2022, 5:12 AM), <https://news.bloomberglaw.com/privacy-and-data-security/new-law-buffers-california-companies-from-abortion-data-requests>.

model attestation. The States recommend that a model attestation at the very least state the circumstances under which an attestation must be submitted.

The Department seeks comment on whether requesters of PHI should be required to name the individuals whose PHI they are requesting, or whether describing a class of individuals whose PHI is requested is sufficient to protect the privacy of individuals. The States believe that a request for PHI should be specific to an individual person for a specific time period in order to protect the privacy interests of patients and ease the administrative burden on covered entities. Requiring that attestations be more detailed lessens the possibility that covered entities will receive requests that are unwarranted fishing expeditions for reproductive health information.<sup>55</sup>

The Department also asks whether to include a signed declaration made under penalty of perjury that the requester is not making the request for a prohibited purpose. The States endorse this proposal as it plainly puts the requester on notice of what criminal statute is implicated if the requester violates the Proposed Rule.

The Department asks whether it should consider it a material misrepresentation if a person who signs an attestation does not have an objectively reasonable basis to suspect that the reproductive health care was provided under circumstances in which it was unlawful, and, if so, what the Department should consider a “reasonable basis for suspicion.”<sup>56</sup> The States endorse this idea. The attestation should include specific language that any requester who is seeking PHI because they believe the reproductive health care provided was not lawful under the circumstances must have a reasonable basis for that belief and that the absence of an articulable, fact-based reasonable suspicion will constitute a material misrepresentation. This prevents fishing expeditions because requesters must have actual, objective reasons to believe a specific individual received care or provided care in violation of that state’s law. Including such notice on the attestation will put the requester on notice that the absence of reasonable basis for suspicion will expose them to potential criminal penalties, including perjury. Since failure to have a reasonable basis for suspicion would subject the requester to criminal liability, we suggest that reasonable basis for suspicion should be defined as “reasonable suspicion” as in the criminal context: the requester must have a particularized and objective basis based on specific and articulable facts that would lead an objectively reasonable person to believe that the reproductive health care provided was unlawful under the circumstances.

The new Attestation Requirement would also require a covered entity to cease the use or disclosure of PHI if it has reason to believe that the representations in an attestation are materially false.<sup>57</sup> The Department acknowledges that “a requester who knowingly falsifies an attestation (*e.g.*, makes material misrepresentations as to the intended uses of the PHI requested) to obtain, or cause to be disclosed, an individual’s IHI [individually identifiable health information] would be in violation of HIPAA and could be subject to criminal penalties as

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<sup>55</sup> Cf. Yasmeen Abutaleb and Emily Wax-Thibodeaux, *Missouri Reviewed Data About Planned Parenthood’s Patients, Including Their Periods, to Identify Failed Abortions*, WASH. POST (Oct. 30, 2019, 6:15 PM), [https://www.washingtonpost.com/health/missouri-tracked-planned-parenthood-patients-periods-in-spreadsheet-top-health-official-says/2019/10/30/e96791d0-fb42-11e9-ac8c-8ecedd29ca6ef\\_story.html](https://www.washingtonpost.com/health/missouri-tracked-planned-parenthood-patients-periods-in-spreadsheet-top-health-official-says/2019/10/30/e96791d0-fb42-11e9-ac8c-8ecedd29ca6ef_story.html).

<sup>56</sup> 88 Fed. Reg. 25337.

<sup>57</sup> See Proposed 45 C.F.R. § 164.509(d).



outlined in the statute.”<sup>58</sup> We note that the relevant statute imputing criminal liability states that a person shall be deemed to have committed a violation if the person “disclosed such information without authorization,” but does not explicitly state that a violation would accrue if the person falsified an attestation.<sup>59</sup> Providing such clarification would give assurance to patients and providers that the falsification of an attestation would lead to criminal consequences for those who falsify attestations. OCR further acknowledges that a falsified attestation “may require notifications of a breach to the individual, the Secretary, and in some cases, the media.”<sup>60</sup> The States suggest requiring that any covered entity who receives a falsified attestation report this to the HHS Secretary. Requiring this reporting would not only assist in OCR’s enforcement of HIPAA violations, but it would also allow OCR to document the issue and provide updated guidance if necessary.

Finally, the Department asks whether alternative documentation may substitute for an attestation, such as notice from a health oversight agency that identifies an objective audit and information sought. The States believe that attestations should always be required. Additional documentation is helpful to covered entities not only to determine whether the PHI is being requested for a legitimate or prohibited purpose, but also serves to put the requester on notice of the prohibited reasons for requesting and using such information and to hold the requester accountable in the event that the PHI is used for a prohibited reason.

## **VI. Recommendations in Support of Excluding Reproductive Health Information from the Authorization Exceptions in Section 164.512**

In line with new prohibited uses and disclosures in Section 164.502 and the new Attestation Requirement in Section 164.509, the Department proposes to amend Section 164.512, which currently allows disclosures of PHI in specific situations without prior authorization by the patient or opportunity to agree. Specifically, Section 164.512 authorizes PHI disclosures for government or administrative functions and national priority purposes.<sup>61</sup> The NPRM carves out exceptions to Section 164.512 related to reproductive health, clarifying that such disclosures are prohibited when they fall under the requirements of proposed Section 164.502(a)(5)(iii), and that covered entities must obtain an attestation from the requester if the disclosure of PHI is potentially related to reproductive health care.

The States welcome the Department’s decision to amend Section 164.512 to provide a necessary safeguard against potential abuse by governmental authorities who aim to stop people from or punish people for seeking, obtaining, or providing lawful abortions. This amendment to Section 164.512 is in line with state-based efforts to protect patients’ right of privacy when it comes to their personal reproductive decisions. For example, in September 2022, the California Legislature passed Assembly Bill 2091, which amends California’s CMIA to prohibit a provider of health care, health care service plan, contractor, or employer from releasing, in response to a

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<sup>58</sup> 88 Fed. Reg. 23536 (citing 42 U.S.C. § 1320d-6(a)-(b)).

<sup>59</sup> See 42 U.S.C. § 1320d-6(a).

<sup>60</sup> 88 Fed. Reg. 23536.

<sup>61</sup> See 45 C.F.R. § 164.512(d) (to a health oversight agency for oversight activities); *id.* at § 164.512(e) (in the course of any judicial or administrative proceeding in response to a court order); *id.* at § 164.512(f) (for a law enforcement purpose to a law enforcement official).

subpoena, medical information related to a person seeking or obtaining an abortion if the subpoena is based on another state's laws that interfere with a person's rights under California's Reproductive Privacy Act.<sup>62</sup> The Proposed Rule creates a federal standard that will unify the requirements of covered entities across state lines.

The Department requests comment on how regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 C.F.R. § 164.512(d), (e), (f), or (g)(1). To the extent the Department seeks information related to the potential administrative burden presented by the proposed prohibition and attestation requirements, the States believe that the privacy interests at stake outweigh any potential administrative burdens. As described in the preamble to the NPRM, access to reproductive health care has undergone a seismic shift since the *Dobbs* decision. The Proposed Rule is a necessary step towards preserving the mandates of HIPAA by shoring up protections for access to confidential reproductive care. The history of HIPAA and its implementation shows that the privacy landscape is constantly evolving, and covered entities must frequently adapt to new rules and regulations.<sup>63</sup> Moreover, some of the States have health privacy laws that are more robust than the HIPAA requirements. For example, in addition to the disclosures that require authorizations under HIPAA, California law requires prior written authorization for disclosures related to drug and alcohol treatment records as well as HIV status.<sup>64</sup> Illinois requires prior written consent for the disclosure of information relating to mental health and developmental disability services.<sup>65</sup> In New York, certain records shall not be released even with an authorization, including those relating to a minor's treatment for a sexually-transmitted infection or the performance of an abortion.<sup>66</sup> Similarly, Washington limits the disclosure of sexually-transmitted diseases<sup>67</sup> and Maine requires that sensitive patient information relating to HIV status, disability, and substance use disorder treatment be kept confidential.<sup>68</sup> While the Proposed Rule's prohibitions and attestation requirements will require administrative changes, the experience of our covered entities under HIPAA's shifting landscape and state-specific health privacy requirements demonstrates that they have implemented similar changes in the past and are capable of doing so again.<sup>69</sup>

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<sup>62</sup> A.B. 2091, 2022 Leg., Reg. Sess. (Cal. 2022) (codified at Cal. Civ. Code § 56.108).

<sup>63</sup> See, e.g., *HIPAA History: When was HIPAA Established?*, THE HIPAA JOURNAL (last visited May 10, 2023), <https://www.hipaajournal.com/hipaa-history/>.

<sup>64</sup> Cal. Health & Safety Code §§ 11845.5, 123105(b), 120975-121125; Cal. Civ. Code § 56.104.

<sup>65</sup> 740 ILL. COMP. STAT. §§ 110/1-17.

<sup>66</sup> N.Y. Pub. Health Law § 17 (McKinney).

<sup>67</sup> WASH. REV. CODE § 70.02.220.

<sup>68</sup> ME. STAT. tit. 34-B, § 1207 (2019) (making orders of commitment and related documents confidential); ME. STAT. tit. 34-B, § 5605(15) (2011) (requiring that records of intellectual disability and acquired brain injury be kept confidential); ME. STAT. tit. 5, § 19203 (1987) (making HIV tests records confidential); ME. STAT. tit. 5, § 19203-D (1999) (preventing disclosure of HIV status); ME. STAT. tit. 24, § 2329(8) (2017) (making substance use disorder treatment records confidential).

<sup>69</sup> The States wish to highlight a parallel NPRM that may provide useful information to OCR on covered entities' capabilities of segmenting data where special handling or other restriction of access to particular portions of electronic PHI is required. On April 18, 2023, HHS and the Office of the National Coordinator for Health Information Technology ("ONC") issued a proposed rule entitled "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing."<sup>69</sup> In the NPRM, ONC acknowledges that the interoperability and electronic exchange of health information are all in the best interest of patients and central to the well-being of all Americans. However, public feedback shows there is significant

We note that the Department says that the Privacy Rule “does not apply to individuals’ health information when it is in possession of a person that is not a covered entity or business associate, such as a friend, family member, or is stored on a personal cellular telephone or tablet.”<sup>70</sup> While we agree that the Privacy Rule does not apply in these circumstances, we believe the Department should clarify that certain state laws may protect this information, such as California’s and New York’s new laws safeguarding abortion data, identified above.<sup>71</sup>

## **VII. Recommendations to Ensure Effective Notice of Privacy Practices for Protected Health Information in Section 164.520**

The States applaud HHS for its consideration of whether an expanded notice of privacy practices (“NPP”) that includes information regarding prohibited uses and disclosures for protected health information is warranted. We endorse such expanded notice, and further recommend that it incorporate protections to ensure the information is made available in a clear and accessible form and that it clarify the circumstances when the recipient of the PHI would not be bound by the HIPAA privacy protections (*i.e.*, when the recipient is not a covered entity). It is a core data privacy principle to inform individuals of how the data they share with an entity will be subsequently used or disclosed so that individuals have an opportunity to provide informed consent before any subsequent uses or disclosures occur. Through the NPP, the Privacy Rule gives individuals a fundamental right to be informed of the privacy practices of their direct treatment providers, and to be informed of their privacy rights with respect to their PHI.<sup>72</sup> Thus, providing consumers with notice and choice as to their health data grants individuals autonomy over the collection and use of their personal health information. As a result, direct treatment providers are required to develop and distribute notices that clearly explain individuals’ rights and prompt individuals to have discussions with their direct treatment providers in exercise of their rights.<sup>73</sup> We applaud the Department’s efforts to make this notice more comprehensive, including notice of both when their PHI *is and is not protected* and when it could be shared with an entity that is not bound by the restrictions of HIPAA.

However, adding more text to long and often difficult to understand NPPs, which patients

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variability in health information technology (“IT”) products’ capabilities to segment data where such segmentation is required or requested, including “cases where special handling or other restriction of access, exchange, or use of particular portion(s) of a patient’s EHI is required by law.”<sup>69</sup> ONC requests information on the capabilities of health IT products to segment data in a variety of contexts including segmenting data “subject to varying state laws requiring special handling or access restrictions in such situations—such as behavioral health information, HIV diagnosis and treatment, genetic testing, treatment of minors, or incidents of sexual violence” and whether “[a]n existing certified EHR system does not have technical capacity to appropriately segment and share specific health information according to applicable laws.”<sup>69</sup> We believe comments to ONC’s proposed rule would contain useful information pertaining to the implementation of the Proposed Rule and request OCR consider how the information provided, particularly from the expertise of health IT professionals, would affect the Proposed Rule.

<sup>70</sup> 88 Fed. Reg. 23538.

<sup>71</sup> See *supra* Section II.

<sup>72</sup> 45 C.F.R. § 164.520; *Notice of Privacy Practices*, U.S. Dep’t Health & Human Servs. (last reviewed Nov. 2, 2020), <https://www.hhs.gov/hipaa/for-individuals/notice-privacy-practices/index.html>.

<sup>73</sup> *Notice of Privacy Practices for Protected Health Information*, U.S. Dep’t Health & Human Servs. (last reviewed July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html>.

may not even fully read or comprehend, is unlikely to result in improved patient awareness of these implications. Accordingly, we recommend HHS make this information more prominent, reemphasize the plain language requirement to covered entities, and update its model forms.

There is ample data indicating that people rarely read privacy policies, much less understand them.<sup>74</sup> There is little doubt that this is likewise true of NPPs.<sup>75</sup> It is crucial that any new required text regarding the uses and disclosures of reproductive health information be presented in a way that gets the reader's attention. To best accomplish this, HHS should require: (1) that uses and disclosures of reproductive health information be prominently displayed on the first page of the NPP and (2) that the NPP include a clear and conspicuous header. A clear and conspicuous header could mean a larger type size than the surrounding text, contrasting type, font, or color to the surrounding text of the same size, or using symbols such as asterisks to set off language from the surrounding text of the same size in a manner that clearly calls attention to the language.<sup>76</sup> Ensuring that this new and highly important text stands out to the reader's eye will help ensure that patients actually see the new information.

There is also an ongoing need to ensure that NPPs are serving their intended purpose by providing easy to understand information to patients regarding their health privacy.<sup>77</sup> HHS should take this opportunity to give more guidance to covered entities by providing additional clarity on what fulfills the "plain language" requirement and by putting out new model NPPs in advance of the effective date of the final rule. Any new guidance should consider how to best ensure comprehension by patients who have limited literacy, limited health literacy, or limited

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<sup>74</sup> See, e.g., Kim Hart, *Privacy Policies are Read by an Aging Few*, AXIOS (Feb. 28, 2019), <https://www.axios.com/2019/02/28/few-people-read-privacy-policies-survey>; Mark Hochhauser, *Why Patients Won't Understand Their HIPAA Privacy Notices*, PRIVACYRIGHTS.ORG (Apr. 10, 2003), <https://privacyrights.org/resources/why-patients-wont-understand-their-hipaa-privacy-notices-hochhauser>; Alex R. Rosenblatt, *I Declined to Share my Medical Data with Advertisers at my Doctor's Office. One Company Claimed Otherwise*, STAT NEWS (Apr. 7, 2023), <https://www.statnews.com/2023/04/07/medical-data-privacy-phreesia/>; Geoffrey A. Fowler, *You Agreed to What? Doctor Check-In Software Harvests Your Health Data*, WASH. POST (June 13, 2022, 5:00 AM), <https://www.washingtonpost.com/technology/2022/06/13/health-privacy/>.

<sup>75</sup> See, e.g., Marie C. Pollio, *The Inadequacy of HIPAA's Privacy Rule: The Plain Language Notice of Privacy Practices and Patient Understanding*, 60 NYU ANN. SURV. AM. L. 579 (Jan. 14, 2005), [http://www.law.nyu.edu/sites/default/files/ecm\\_pro\\_064663.pdf](http://www.law.nyu.edu/sites/default/files/ecm_pro_064663.pdf) (arguing HHS does not go far enough in defining plain language and that there is a need for a more objective measure of readability with respect to the NPP plain language requirement).

<sup>76</sup> The Federal Trade Commission's guidance on what constitutes a clear and conspicuous disclosure may also be useful to HHS when considering how the Rule's protections should appear on the NPP. See Federal Trade Commission, ".com Disclosures: How to Make Effective Disclosures in Digital Advertising" (Mar. 2013), <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf>.

<sup>77</sup> The regulations for the California Consumer Privacy Act (CCPA) expressly require that disclosures to consumers take a performance-based approach by requiring that privacy policies and notices are "easy to read and understandable to consumers." CAL. CODE REGS., tit. 11, § 7003. Disclosures must be in a readable format, available in various languages, and be accessible to consumers with disabilities. These requirements were borne from studies that found that presentation and the use of plain language techniques positively influence the effectiveness and comprehension of privacy policies. See Florian Schaub, et al., *A Design Space for Effective Privacy Notices*, 2015 Symposium on Usable Privacy and Security (SOUPS), (July 22-24, 2015), <https://www.usenix.org/system/files/conference/soups2015/soups15-paper-schaub.pdf>; CTR. FOR PLAIN LANGUAGE, *PRIVACY-POLICY ANALYSIS* (2015), <https://centerforplainlanguage.org/wp-content/uploads/2016/11/TIME-privacy-policy-analysis-report.pdf>.

English proficiency. For example, HHS could identify a minimum recommended score for readability on the Flesch-Kincaid test.<sup>78</sup> In determining the appropriate level and revising the model NPP language, HHS should conduct readability screenings, seek and receive stakeholder input, and conduct beneficiary testing to ensure broad readability.

### **VIII. The States Encourage OCR to Create a Centralized Platform that Provides Education on Reproductive Care and Privacy Rights**

As outlined above, the States are in support of the Proposed Rule because it is a necessary step to increase protections for reproductive health privacy for those travelling out of state for abortion care and providers who practice in states where abortion is legal. It is not lost on the States, however, that reproductive health disparities at the state level are growing. While the Proposed Rule is essential to begin creating a more unified privacy landscape for access to reproductive care, legislative efforts to greatly restrict or ban access to abortion and access to reproductive health care are only gaining traction. This has resulted in a disjointed landscape for reproductive health services and has led to confusion among patients and providers and other covered entities. During this time of great upheaval, health literacy has never been more crucial for the public health.<sup>79</sup> The States urge OCR to emphasize the education of people seeking health care by creating a nationally available, online platform that provides accurate and clear information on reproductive health care and privacy rights. To reach the largest audience, the States encourage OCR to make this information available in multiple languages and in alignment with accessibility principles. In order for this information to best reach the public, OCR could conduct a public awareness campaign to promote the website. The States believe that education and outreach will be a necessary component for successful implementation of the Proposed Rule and the preservation of access to reproductive health care going forward.

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<sup>78</sup> See *Flesch Reading Ease and the Flesch Kincaid Grade Level*, READABLE (last viewed May 19, 2023), <https://readable.com/readability/flesch-reading-ease-flesch-kincaid-grade-level/> (“Flesch readability scores are the most popular and are the most widely tested and used.”).

<sup>79</sup> See Eric D. Perakslis et al., *Proposed Rules to Protect Health Data in an Era of Abortion Bans Fall Short*, STAT NEWS (May 12, 2023), <https://www.statnews.com/2023/05/12/hipaa-abortion-health-data-privacy-draft-rulemaking/>.

## CONCLUSION

For the foregoing reasons, the signatory States strongly support the increased privacy protections offered by the Proposed Rule, which will provide much-needed updates for the digital age, offer essential guidance to covered entities, and help shore up protections for critical reproductive health care. Further, in order to further strengthen these necessary safeguards, we urge the Department to implement the above improvements to the final Rule. The Department's swift action in implementing these necessary protections is a vital step in defending sensitive reproductive health information against disclosure to the maximum extent possible in today's rapidly-shifting and increasingly hostile climate.

Sincerely,



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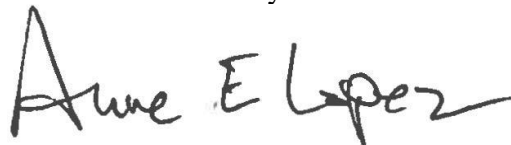
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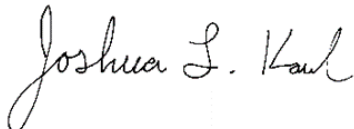
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