# NCVHS
## National Committee on Vital and Health Statistics

June 14, 2023

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

**Re: Comments on Docket # HHS-OCR-2023-0006, Notice of Proposed Rulemaking, "HIPAA Privacy Rule to Support Reproductive Health Care Privacy"**

Dear Mr. Secretary:

On behalf of the National Committee on Vital and Health Statistics (NCVHS, Committee), I am pleased to provide our comments on the notice of proposed rulemaking (NPRM), "Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care Privacy."

NCVHS is your advisory body on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA).[1] Among its duties, NCVHS is charged with studying and identifying "privacy, security and access measures to protect individually identifiable health information in an environment of electronic networking and multiple uses of data."[2] Within the past two decades, NCVHS has advised the Department's Secretaries on a range of matters regarding HIPAA's Privacy and Security Rules, offering advice on areas where protections can be improved.

The NPRM would modify the regulations laying out Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule")[3] promulgated under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act).[4] In the preamble, the Department specifically invites the Committee to comment.

NCVHS appreciates being invited to review the proposed rule and to provide comments to the Department. We congratulate the Department for the foundational work done in drafting this notice of proposed rulemaking, and we are particularly pleased that much of the Committee's past work regarding sensitive health information found in medical records, including, among other categories, reproductive health information, has been cited in the proposed rule.

[1] Health Insurance Portability and Accountability Act, Pub. L. 104-191, 100 Stat. 2548 (1996).
[2] Charter, National Committee on Vital and Health Statistics (Jan. 21, 2022), available at https://ncvhs.hhs.gov/about/charter/ (visited May 17, 2022).
[3] 5 CFR Part 160 and 5 CFR Part 164, Subparts A and E.
[4] Title XIII of Pub. L. 111-5, 123 STAT. 226 (2009).

NCVHS supports the Department's efforts to protect privacy, promote the dissemination of accurate health information, and ensure access to reproductive health care. We agree with the statements in the preamble to the NPRM, that "the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* (*Dobbs*) makes it more likely than before that individuals' PHI [protected health information] may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect," that the new legal environment is likely to "chill access to lawful health care and full communication between individuals and health care providers," and that it "increases the potential for uses or disclosures about an individual's reproductive health to undermine access to and the quality of health care generally."[5]

We also agree with the statement following the April meeting of the Taskforce on Reproductive Healthcare Access that "efforts to protect sensitive health information, including related to reproductive health care, have taken on renewed importance, as states seek to penalize and criminalize health care providers and interfere in deeply personal medical decisions."[6]

In carrying out our analysis, the Committee holds to the principle that has been at the core of our work for over 25 years: medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law enforcement or other governmental purposes.[7] In particular, medical records should not be used against a patient, a provider,[8] or any third party merely for seeking, obtaining, providing, or facilitating health care.

While we appreciate the Department's action to further safeguard reproductive health information and preserve the confidentiality of the patient-provider relationship by restricting certain uses and disclosures of PHI for non-health care purposes, we also ask that the Department consider our recommendations regarding the feasibility of implementation as drafted, and provide the following comments for your consideration.

In summary, our comments are as follows:

1. To reduce the likelihood health records may be employed to harm patients or others for seeking, obtaining, providing, or facilitating health care, the Department should examine not making a distinction between care provided that is illegal v. legal.
2. The Department should examine prohibiting disclosures for a criminal, civil, or administrative

[5] Id.
[6] White House, "Fact Sheet: Biden-Harris Administration Announces Actions to Protect Privacy at the Third Meeting of the Task Force on Reproductive Health Care Access," (April 12, 2023), available at https://www.whitehouse.gov/briefing-room/statements-releases/2023/04/12/fact-sheet-biden-harris-administration-announces-actions-to-protect-patient-privacy-at-the-third-meeting-of-the-task-force-on-reproductive-healthcare-access/.
[7] NCVHS, Letter to Secretary Donna Shalala transmitting *Health Privacy and Confidentiality Recommendations*, June 25, 1997 (stating, "when identifiable health information is made available for non-health uses, patients deserve a strong assurance that the data will not be used to harm them."), available at https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/
[8] We understand that some health care professionals may not be considered covered entities directly. When we use the term "covered entity" we mean a covered entity as defined in the HIPAA Privacy Rule. However, when we use the term "provider," we are less precise and intend to include health care professionals that may not be covered entities.

investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating *any* health care, not just reproductive health care.

3. *If* the final rule continues to prohibit use and disclosure under 164.512(d), (e), (f), and (g) of PHI "in connection with seeking, obtaining, providing, or facilitating reproductive health care,"[164.502(a)(5)(iii)(A)] then we recommend the Department consider reworking the definition of reproductive health care to include specific, encompassing, and clear terms, informed by the exposition in our comments.
4. To reduce uncertainty and burden among covered entities, and to make the rule more feasible to implement, the Department should examine requiring attestations under 164.512(d), (e), (f), *and* (g) for all requests for PHI, rather than limiting the requirement to requests that are "potentially related to reproductive health care" because the definition is so broad that in practice it would approach encompassing all PHI.
5. *If* the final rule continues to require attestations under 164.512(d), (e), (f), and (g) for requests for PHI that includes reproductive health care or PHI "potentially related to reproductive health care" [164.509(a)] then we recommend the Department consider reworking the definition of reproductive health care to include specific, encompassing, and clear terms, informed by the exposition in our comments.
6. If the Department maintains a definition of "reproductive health care," as an alternative, we recommend the Department define the term more precisely with the use of specific, encompassing, and clear terms in the regulatory text and provide examples of diverse types of reproductive health care.
7. To effectuate protections for privacy of health information and access to reproductive and other health care, we recommend the Department consider employing all available authorities at its disposal.
8. We recommend the Department examine the definition of "public health" in 160.103 as it applies to surveillance, investigation, and intervention and consider further clarifying the relationship between this definition and the terms "civil or authorized investigative demands," in 164.512(f). This is to ensure that public health activities associated with individual-level public health investigations and interventions are addressed in the way intended, and the rule does not produce unintended consequences on public health investigations or individual level activities.
9. The Department should examine whether the definition of de-identified data as used in this proposed rulemaking is appropriate and should consider the earlier recommendations made by NCVHS in its 2017 letter to the Secretary.[9]
10. We recommend that the Department consider adding a requirement in the final rule that an attestation include a statement that the recipient of health records pledges not to redisclose the records to another party for any of the prohibited purposes named in the attestation.
11. We recommend that the Department consider specifying language for the Notice of Privacy Practices in plain language that is clear and understandable to all patients.

[9] Recommendations on De-identification of Protected Health Information under HIPAA https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2017-Ltr-Privacy-DeIdentification-Feb-23-Final-w-sig.pdf

12. We recommend that the Department consider addressing the relationship of the rule to health information access and exchange, including in telehealth, telemedicine, medical devices, apps, wearables, interoperability, information blocking, and the 21st Century Cures Act Trusted Exchange and Common Agreement (TEFCA).

We appreciate the opportunity to offer these comments and look forward to working with the Department further to ensure the privacy of patients and their access to reproductive health care.

Sincerely,

/s/
Jacki Monson, J.D., Chair
National Committee on Vital and Health Statistics

Enclosure

**Comments of the**
**National Committee on Vital and Health Statistics**
**on the**
**HHS Notice of Proposed Rulemaking**
**"HIPAA Privacy Rule to Support Reproductive Health Care Privacy"**

**Applicability and Scope**

The purpose of the proposed rulemaking is to protect access to reproductive health care by limiting uses and disclosures of an individual's protected health information (PHI) where it could be used for punitive non-health care purposes. The proposal does this by prohibiting the use or disclosure of PHI for the criminal, civil, or administrative investigation of or proceeding against an individual, regulated entity, or other person for seeking, obtaining, providing, or facilitating reproductive health care, or the identification of any person for the purpose of initiating such an investigation or proceeding. It circumscribes the scope of prohibited disclosures to circumstances when the reproductive health care:

> (1) is provided outside of the state where the investigation or proceeding is authorized and where such health care is lawfully provided;
>
> (2) is protected, required, or authorized by Federal law, regardless of the state in which such health care is provided; or
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> (3) is provided in the state in which the investigation or proceeding is authorized and that is permitted by the law of that state.

The preamble explains that, in these three circumstances, the state lacks any substantial interest in seeking the disclosure.

The Committee has carefully considered and debated the scope and applicability of the proposed rule and recommends that the Department consider expanding the scope of the rule's applicability as discussed below.

*Lawful v. unlawful care*

We agree that the state lacks substantial interest in the above types of disclosures. In addition, we ask the Department to consider eliminating the NPRM's distinction between care that is lawful and care that is not. In carrying out our analysis, the Committee holds to the principle that has been at the core of our work for over 25 years: medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law enforcement or other

governmental purposes.[10] In particular, medical records should not be used against a patient, a provider, or any third party merely for seeking, obtaining, providing, or facilitating health care.

The NPRM recognizes that states and localities have instituted or threatened civil, criminal, or administrative investigations or proceedings on the basis of reproductive health care that is lawful under the circumstances in which it was provided.[11] This points to a difficulty on the part of patients, providers, and law enforcement entities of knowing definitively, at the moment a patient presents for care, whether the care is legal in that circumstance.

Whether a particular treatment is legal or illegal may not be apparent to either the patient or the provider at the time a patient seeks care. Nevertheless, patients should be encouraged to seek care when necessary, without fear that they must first consult an attorney to ensure that the care is legal. Legal counsel may be unavailable, obtaining counsel may be prohibitively costly, and seeking counsel could delay necessary care. If a patient or a provider cannot definitely know at the time care is sought whether that care is legal and knows that the resulting medical records could be obtained to support legal action if the care is determined not to be legal, the patient may be reluctant to seek care, to be candid with the physician, or to disclose other important health conditions, even those unrelated to reproductive health care.

Similarly, it would be unwise for providers to have to perform the same calculus when a patient presents with a complicated case, and it would be contrary to health care ethics and norms and to fundamental tenets of public health, to require a provider to do so. The provider could be inhibited in providing necessary treatment, in fully educating patients about potential medical options, or in documenting the given care appropriately for similar reasons.

These circumstances may not be rare, but routine,[12] and therefore could produce risks that the Department has stated it intends to avoid: future doctors choosing to forego medical school, medical

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[10] NCVHS, Letter to Secretary Donna Shalala transmitting *Health Privacy and Confidentiality Recommendations*, June 25, 1997 (stating, "when identifiable health information is made available for non-health uses, patients deserve a strong assurance that the data will not be used to harm them."), *available at* https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/.

[11] See, e.g., Gilbert A. "After miscarriage, woman is convicted of manslaughter. The 'fetus was not viable,' advocates say." USA TODAY, (Oct, 21, 2021)(describing the case of a 20-year-old woman convicted of manslaughter in Oklahoma and sentenced to four years after suffering a miscarriage), available at https://www.usatoday.com/story/news/nation/2021/10/21/oklahoma-woman-convicted-of-manslaughter-miscarriage/6104281001/;

[12] Fingar KR (IBM Watson Health), Mabry-Hernandez I (AHRQ), Ngo-Metzger Q (AHRQ), Wolff T (AHRQ), Steiner CA (Institute for Health Research, Kaiser Permanente), Elixhauser A (AHRQ). Delivery Hospitalizations Involving Preeclampsia and Eclampsia, 2005–2014. HCUP Statistical Brief #222. April 2017. Agency for Healthcare Research and Quality, Rockville, MD. www.hcupus.ahrq.gov/reports/statbriefs/sb222-Preeclampsia-Eclampsia-Delivery-Trends.pdf A potentially relevant example, the Agency for Healthcare Research and Quality in 2017 reported that in 2014, almost five percent of all inpatient deliveries involved

professionals choosing not to practice in states where the full range of care is not permissible,[13] and a reduction in access to care in some states leading to worse health outcomes and an increase in disparities across populations. Eventually these impacts could threaten public health more generally, and the health care system as a whole.

We acknowledge that state legislatures may pass or uphold laws addressing concerns of their constituencies. However, in order to preserve patient trust in, and the viability of the nation's health care and public health systems, it is appropriate for federal law and policy to protect medical records from being used in a legal action that would punish any person merely for seeking, obtaining, providing, or facilitating access to health care.

The HIPAA privacy rule has never protected patient privacy absolutely; it has always permitted some disclosures of PHI without the patient's consent to uphold other values and public policy deemed to override the patient's privacy interests, including in legal and oversight activities. These include disclosures to support criminal, civil, and administrative law enforcement; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities.

The proposed rule seeks to continue to address these needs in the face of a changing legal environment that threatens to reduce trust in health care providers, health care organizations, and the public health system. However, we believe that attempting to distinguish between requiring attestations only where the care is legal would be unwise. Even where a state has an interest in regulating, and even were it possible to distinguish at the moment of care whether the care is legal, it would still be inappropriate to employ medical records against any person in a legal action that would do them harm merely for seeking, obtaining, providing, or facilitating health care.

It is also well-established in 42 CFR Part 2, the regulations on confidentiality of substance use treatment records, that it is legally possible to protect the privacy of patients who may be engaging in illegal activity to uphold other public policy principles and public health goals, and, in such circumstances, prevent access to medical records even by court order without the consent of the patient.

Therefore, we recommend the Department consider deleting the proposed language in 160.502(a)(5)(iii)(C)(1) that states "where such health care is lawful in the state in which it is provided"

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preeclampsia/eclampsia—a 21 percent increase from 2005. Preeclampsia is a disorder of new-onset high blood pressure occurring after 20 weeks of gestation, and after many states prohibit abortion. In addition to increased risk of mortality, women with preeclampsia/eclampsia are more likely to experience cesarean section, placental abruption, disseminated intravascular coagulation, cerebral hemorrhage, pulmonary edema, and renal failure. See AHRQ, Healthcare Cost and Utilization Project Statistical Brief #222: *Delivery Hospitalizations Involving Preeclampsia and Eclampsia, 2005–2014* (April 2017), available at https://hcup-us.ahrq.gov/reports/statbriefs/sb222-Preeclampsia-Eclampsia-Delivery-Trends.pdf

[13] Wernau, Julie. "State Abortion-Law Changes Upend Medical Training Programs; Some medical students limit residency searches to states that allow abortion". Wall Street Journal. October 06, 2022. Available here: https://www.wsj.com/articles/state-abortion-law-changes-upend-medical-training-programs-11665020346

and deleting the proposed language in 160.502(a)(5)(iii)(C)(3) that states "and that is permitted by the law of that state."

It important to note that applying an attestation requirement would not limit access to the records themselves, only the ability to use the records to bring an action against the patient, provider, or third party for the mere act of seeking, obtaining, providing, or facilitating health care. Neither the proposed rule nor the Committee's suggestion that attestations be required in cases where the care may later be found unlawful prevent a state from pursuing legal actions. Medical records would still be available for some purposes, but the role of the Department as a health care and public authority is to ensure medical records are not used to harm the patient who is the subject of those records, nor providers or others who provide or facilitate care, nor the system that provides care and ensures the public's health.

*Disclosures required by law*

We address the possibility that a state would pass a law requiring a provider to disclose reproductive health information to support a legal action against a person for seeking, obtaining, providing or facilitating reproductive health care, and the HIPAA Privacy Rule would permit such a disclosure under 164.512(a). This could be construed to provide an avenue for disclosure of medical records for use in a legal action that the rule intends to prohibit.

The HIPAA Rule at 45 CFR 164.512(a) permits disclosures required by law if they also comply with either 164.512(c), (e), or (f). The structure of the amendments proposed by the NPRM are designed to minimize the ability to use PHI to bring an action against a patient, provider, or third party merely for seeking, obtaining, providing, or facilitating reproductive health care. Under 164.512(c) the proposal specifically excludes disclosures where "the report of abuse, neglect, or domestic violence is based primarily on the provision of reproductive health care." In the case of (e) and (f), an attestation would be required thus preventing the use of the records to target a patient, provider, or third party for merely seeking, obtaining, providing, or facilitating reproductive health care. With the exception of our concerns about the potential problems with the definition and use of the term "reproductive health care," we concur in this result and suggest the Department clarify in the preamble that this is the Department's intention.

*Disclosures where PHI is "potentially related to reproductive health care"*

The proposed rule would prohibit use or disclosure of PHI "potentially related to reproductive health care" for purposes specified in § 164.512(d),(e),(f), or (g) without obtaining an attestation prohibiting the use of PHI for

> (1) a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care; or

(2) to identify any person for the purpose of initiating of the same activities.[14]

The preamble discusses the fact that reproductive health care is not easily defined, and that reproductive health information is not able to be fully segmented or segregated in the patient's medical record. NCVHS observes that reproductive health care information may be present in seemingly unrelated visits, chart notes, test results, and medication lists. For example, any patient potentially pregnant is likely to be tested for pregnancy in an emergency room before a clinician would prescribe certain treatments or administer medication. Patients of childbearing age are routinely asked if they are pregnant before a radiological exam.

In a large facility, reproductive health information is potentially found in every department, in every record, and in every system including those that may not have a readily apparent relationship to reproductive health care. For smaller entities, records are also likely to be commingled so that it could be onerous and costly to separate different types of health information in a medical record. Even if the technology to segment separate records effectively were to become available and affordable in the future, it could be challenging and cost prohibitive, or technically infeasible, to attempt to treat information potentially related to reproductive health differently than all other data. A broad and nonspecific definition of "reproductive health care," as proposed in the NPRM, could therefore be unduly burdensome or technically infeasible for covered entities to implement.

We note that Congress has required greater alignment of the 42 CFR Part 2 regulations on the confidentiality of substance use disorder treatment records with certain aspects of the HIPAA Privacy Rule in response to similar challenges and the desire for better care coordination.[15] The Department has taken steps toward this harmonization with a separate NPRM on that topic.[16] The definition of *reproductive health care* in the proposed rule, being necessarily broad, and the language in proposed 164.509(a) that prohibits use or disclosure "of protected health information *potentially related* to reproductive health care" [emphasis added], which expands the prohibition further, could together be construed to eliminate the distinction of reproductive health care records from other records. In practice, we believe this use of the definition is so broad that in practice it would approach encompassing all PHI as subject to the new prohibitions.

Because we hold firm to the principle, as stated at the beginning of these comments, that patient records should not be used for purposes outside of the health care setting that could harm the patient, this does not particularly trouble us. Individuals should feel safe seeking any type of health care, not just reproductive health care. NCVHS therefore suggests the final rule recognize this reality by extending the enhanced privacy protections and applying the prohibition broadly to all PHI rather than asking CEs to determine which requests are "potentially related to reproductive health care." In other words, we

[14] See proposed 164.502(a)(5)(iii)(A), NPRM, at 23552.
[15] See Section 3221 of the Coronavirus Aid Relief and Economic Security (CARES) Act, Pub. L. 116–136, 134 Stat. 281, 375 (Mar. 27, 2020).
[16] See HHS, Proposed Rule: "Confidentiality of Substance Use Disorder (SUD) Patient Records," 87 Fed. Reg 72416 (Dec. 2, 2022).

suggest the Department consider requiring an attestation from parties subject to 164.512(d), (e), (f), and (g) regardless of the content of the PHI requested.

This approach recognizes the importance of maintaining trust in the provider-patient relationship so that patients do not withhold information about their health from their providers out of fear of facing prosecution. It also promotes administrative efficiency by reducing uncertainty related to appropriately identifying to which services the enhanced privacy protection should apply. Moreover, requiring parties to determine in advance whether particular records they seek contain anything related to reproductive health could be very burdensome too. And since, as we have stated, reproductive health records might be found in almost any department of a large facility and in any of numbers of places in a record, even using a definition of "reproductive health records" is likely to require an attestation in every case.

*Prohibited purposes for use or disclosure of PHI*

The definition of "reproductive health care" is also used to define the purposes for which use and disclosure of PHI is prohibited by 45 CFR 164.502(a)(5)(iii). If the Department adopts in the final rule the structure laid out in the NPRM — that is, requiring an attestation from certain parties that they do not seek the records in order to initiate or pursue legal action against a provider or patient—we recommend the Department consider applying the prohibition to the seeking, obtaining, providing, or facilitating of *all* health care, not just reproductive health care.

Such a rule would better protect access to reproductive health care by alleviating some of the risk of exposure that would otherwise force a provider to take an action that would be undesirable:

- To hesitate to treat an emergent patient or withhold appropriate treatment until the patient's condition is so severe that there would be no question the Emergency Medical Treatment and Labor Act[17] applies.[18] This has the consequence of causing the patient to endure more serious risk than necessary, increasing costs for the hospital and the responsible payer, and imposing burdens on the health system and public health as a whole.
- To hesitate to prescribe or dispense medications in states where they are labeled as abortifacients (such as methotrexate), posing significant risks to the ability to provide appropriate treatment not just for reproductive care, but for other conditions. Restricting access

[17] EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272, codified at 42 USC § 1395dd. It requires examination and treatment for emergency medical conditions and women in labor. Congress incorporated these antidumping provisions within the Social Security Act to ensure that any individual with an emergency medical condition, regardless of the individual's insurance coverage, is not denied essential lifesaving services.

[18] See, e.g., Simmons-Duffin, Selena. "In Oklahoma, a woman was told to wait until she's 'crashing' for abortion care'. NATIONAL PUBLIC RADIO (April 25, 2023). Available at https://www.npr.org/sections/health-shots/2023/04/25/1171851775/oklahoma-woman-abortion-ban-study-shows-confusion-at-hospitals; PBS News Weekend, "Texas woman describes ordeal with state abortion law after miscarriage," (July 22, 2022)(interview with a woman who miscarried then begged her doctor for help but was instead forced to live for at least two weeks with fetal remains inside her) *available at* https://www.pbs.org/newshour/show/texas-woman-describes-ordeal-with-state-abortion-law-after-miscarriage.

to critical, affordable medicine that is used for a wide range of medical interventions will have detrimental effects on patients' health.[19]

- To hesitate to pursue medicine as a profession, or to practice obstetrics or emergency medicine in states where restrictions on care are established, decreasing access to care and burdening patients and the public's health.[20]

We are concerned that the NPRM's definition of "reproductive health care" is too broad to be operationally meaningful in many settings. A uniform requirement for an attestation as described in the rule that applies to all requests for PHI might simplify processes and reduce burden for both covered entities and requesters and may increase the ability of covered entities to comply.

In addition, limiting the prohibition to the seeking, obtaining, providing, or facilitating of reproductive health care, given the necessarily broad definition, complicates the interpretation and explanation of the definition to patients, employees during training, and throughout various healthcare operations and processes, which may introduce confusion and inconsistency in application. Without clarity, it becomes challenging for these entities to navigate the scope of reproductive health care accurately.

*Disclosures about victims of abuse, neglect, or domestic violence*

Where the Privacy Rule permits the use or disclosure of PHI to report known or suspected abuse, neglect, or domestic violence if the report is made to an appropriate governmental authority, HHS now proposes to clarify that "child abuse" as used in the Privacy Rule excludes a "report of abuse, neglect, or domestic violence. . . based primarily on the provision of reproductive health care.[21] We support this provision and recommend that HHS consider broadening the clarification to include providing or facilitating all health care. This would reduce ambiguity and burden on providers, as we have stated above, in determining what precisely is reproductive health care and provide protection for preventive, behavioral, or other types of health care, or a third party facilitating such health care, that might otherwise be the subject of such a report.

*Reporting crime on premises*

One of the cases in which the above situation may be relevant is the case of reporting crime on the premises of a covered entity. Under the current HIPAA Privacy Rule, a covered entity may disclose to a law enforcement official PHI that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.[22] In states where certain types of

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[19] See, e.g., Shepherd, Katie, and Stead S. Frances. "For the Chronically Ill, a Domino Effect from Abortion Bans." THE WASHINGTON POST (Aug 11 2022) Available at: https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/.

[20] See Fenit Nirappil and Frances Stead Sellers, "Abortion ban states see steep drop in OB/GYN residency applicants," WASHINGTON POST (April 21, 2023) *available at* https://www.washingtonpost.com/health/2023/04/21/abortion-ban-states-obgyn-residency-applications/.

[21] See proposed 45 CFR 160.512(c), NPRM at 23553.

[22] See 45 CFR 64.512(f)(5).

health care are considered a crime, the mere seeking, obtaining, providing, or facilitating the care may be considered a crime that may be reported under this provision. For similar reasons as the new limitations on reporting of suspected child abuse or neglect, we suggest that OCR consider adopting language explicitly excluding conduct based solely on seeking, obtaining, providing, or facilitating health care.

*Reporting crime in an emergency*

Under the current HIPAA Privacy Rule a covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose PHI to a law enforcement official in certain circumstances.[23] In states where certain types of health care are considered a crime, the mere seeking, obtaining, providing, or facilitating the care may be considered a crime that may be reported under this provision. For similar reasons as the new limitations on reporting of suspected child abuse or neglect, we recommend that OCR consider adopting language that would explicit exclude conduct based solely on seeking, obtaining, providing, or facilitating health care.

*Provisions related to conducting investigations*

Under the provisions relating to conducting investigations, NCVHS recognizes the importance of law enforcement to civil society and the integrity of the health care system itself. By suggesting that the Department broaden the requirement that entities obtaining information under 164.512(d), (e), (f), and (g) must present an attestation to obtain records, NCVHS suggests that the attestation requirement does not prevent such an entity from seeing or using the records except in the case of an investigation that would target the patient for seeking or obtaining health care, a provider from offering or providing health care, or any other party assisting in the provision of health care, including transportation and other adjunct services necessary to the provision of care. We strongly/ believe that a patient's medical record should not be used to harm them for merely seeking or obtaining health care and should not impede anyone facilitating or providing that care. To that end, the attestation requirement, if broadened to apply to all requests for PHI, should be clarified on this point.

We intend that the suggestion to require an attestation under 160.5129(d), (e), (f), and (g) , if adopted by the Department, would continue to permit appropriate law enforcement actions such as to investigate fraud, failure of a provider to be properly licensed, failure of a provider to provide competent and professional care, failure of health care facilities to meet licensing and certification requirements, and other infractions where the purpose is not to target

- the patient for merely seeking, accessing, or obtaining care
- a provider or educator for merely providing, training, educating, or facilitating any type of health care; or
- any other party for merely assisting in the provision of health care, including transportation and other adjunct services necessary to the provision of care.

[23] See 45 CFR 64.512(f)(6).

We recognize that HIPAA was originally designed to protect only the privacy of patients, and not any other party, and that the NPRM now seeks to provide some protections for providers and other parties facilitating reproductive health care. We concur in the appropriateness of these provisions. However, we understand that the case of providers is more complicated than the case of patients.

As states consider or adopt new legislation that makes certain types of health care illegal, states may have an interest in targeting for law enforcement attention providers who are seen as practicing medicine that does not meet the standard of care in that state. We understand that such actions are necessary to the integrity of the medical system and the safety of patients, but we support the intention of the Department to protect providers who may be called on to give care in emergent or ambiguous situations that could later be second-guessed through legal actions.

That is, where certain health care services are made unlawful in a state, providing such services would arguably not meet the standard of care in that state. We suggest that the Department consider how best to protect medical professionals in these situations and examine whether it is desirable to establish uniformity across the states as to what constitutes the standard of care relevant to an action prohibited by an attestation under the Privacy Rule. For example, the Department might define or clarify that the language of an attestation prohibits the applicable standard of care as understood by the relevant, recognized, national practice board that certifies providers in the relevant specialty, such as the American College of Obstetrics and Gynecology.

**Definitions**

*Reproductive Health Care*

The definition of reproductive health care is used in two ways in the proposed rule. First, to describe the types of records to which an attestation applies, i.e., PHI "potentially related to reproductive health care." Earlier in our comments, we stated that attestations in the cases where they are required should apply to any request for PHI, and not just in cases "potentially related to reproductive health care."

The second use of the definition of reproductive health care is in the prohibition on the uses or disclosures that may be made of PHI. The proposed rule prohibits the use or disclosure of PHI for "a criminal, civil or administration investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care."[24] In this application of the definition, we also suggest that the prohibition on use or disclosure of records would better protect reproductive health care if it applied generally to the seeking, obtaining, providing, or facilitating of *any* health care.

We do not believe that requiring an attestation for every request under Uses and Disclosures Required by Law 164.512(e) or (f) would add significantly to the burden of those requesters. Under the current HIPAA Rule, the parties seeking records under those provisions must already present some information prior to obtaining information under the rule. The preamble to the proposed rule states that "uses and

[24] Proposed 164.502(a)(5)(iii)(A), NPRM at 23552.

disclosures of PHI for these purposes would be subject to an additional condition; that is, such uses and disclosures would be prohibited unless a regulated entity first obtained an attestation from the person requesting the use and disclosure under proposed 45 CFR 164.509."[25] We interpret this provision not as imposing a separate, additional administrative requirement, but merely an additional condition. An attestation may require different wording than is now required, but in most cases it does not seem to require documentation where none was required before, except, potentially, in the case of coroners.

Finally, we have observed that in the year since *Dobbs*, every day states are considering and adopting new laws, not necessarily related to abortion, that would change what types of care or circumstances of providing health care are legal. Expanding the requirement for an attestation in all cases where parties under 164.512(d), (e), (f), and (g) seek PHI would protect reproductive health care and all other types of health care while reducing the burden on both providers of care and requesters of records to parse out a difficult and ambiguous definition.

An important consideration is to note that nothing in the current rule or the proposed rule, nor in what is suggested for consideration here by NCVHS, would prevent any of the parties who may now obtain information from obtaining it. The proposed rule, and, if our suggestions were adopted, those provisions, would merely require an attestation as to how the records would be used after they are obtained. The records may still be inspected, and copies obtained, in all cases in which they are now available.

Regarding the definition of "Reproductive Health Care," the preamble states:

> In keeping with the Department's intention for ''reproductive health care'' to be interpreted broadly and inclusive of all types of health care related to an individual's reproductive system, the Department would interpret ''reproductive health care'' to include, but not be limited to: contraception, including emergency contraception; pregnancy-related health care; fertility or infertility-related health care; and other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system. Pregnancy-related health care includes, but is not limited to, miscarriage management, molar or ectopic pregnancy treatment, pregnancy termination, pregnancy screening, products related to pregnancy, prenatal care, and similar or related care. Other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system includes health care related to reproductive organs, regardless of whether the health care is related to an individual's pregnancy or whether the individual is of reproductive age.[26]

If the Department maintains a definition of "reproductive health care," as an alternative, we recommend the Department define the term more precisely with the use of specific, encompassing, and

[25] NPRM, at 23538.
[26] See NPRM at 23527

clear terms in the regulatory text and provide examples of diverse types of reproductive health care. Given that state laws are changing every day, what constitutes legal care is subject to frequent change. Therefore it may be important to make explicit what the Department intends to include in plain language. We read the definition in the proposed rule as very broad, and based on its language, we believe that it may be construed to include such things as counseling, hormone therapy, or gender affirming care, even though these things are not explicitly identified.

We suggest that the Department may wish to provide specific examples to illustrate its meaning where that may be ambiguity. Ideally these would be provided in the rule itself, but also would be very helpful in the preamble to the final rule or in subsequent guidance. In so doing, the Department should consider the burden ambiguity may place on providers who will have to explain these definitions to patients, to employees during training, and throughout various healthcare operations and processes. Without clarity, it becomes challenging for these entities to navigate the scope of reproductive health care accurately. To clarify this definition, it could be helpful and assist implementation if the Department were to use its adopted information standards[27] to publish specific lists of procedures, conditions, findings, medications, tests, and other information that constitutes reproductive healthcare.

The "edge cases" or nuances may be difficult to parse for patients or for providers who have to decide when to ask for an attestation based on whether information requested is "potentially related to reproductive health care" under 164.509(a). Since the rule requires an attestation based not just on what is in the definition itself, but also information that is "related to" the definition of reproductive health care, and further what is "potentially related to reproductive health care," the term's use in the rule seems to be much broader than what is apparent in the definition itself. This attenuated language may increase the chilling effect of new state laws and reduce trust in the patient-provider relationship.

Finally, without a more detailed and specific definition in the rule, health care procedures, medications, or diagnoses not intended to be covered could be swept in, adding to the burdens on patients, providers, or requesters. For example, the Department may wish to make clear whether it intends to include information about medications used in the treatment of uterine cancer, or rheumatology, or acne, or when drugs for those conditions may be toxic to a fetus resulting in mandates for laboratory test results and other documentation in order to receive treatment.

Broadening the definition of reproductive healthcare to include all healthcare could have the advantage of making attestation requirements a procedural norm. Requiring requesting parties to provide attestations regularly ensures that the burden of determining when an attestation is needed is shifted to the requesting party. This can create a standardized and predictable process, alleviating the responsibility be placed on healthcare providers to navigate complex and nuanced definitions of reproductive healthcare.

[27] See, Office of the National Coordinator for Health Information Technology (ONC), United States Core Data for Interoperability, Version 1 (July 2020), *available at* https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf.

*Public health*

With regard to the new definition of "public health," the NPRM, states as follows:

> Public health, as used in the terms ''public health surveillance,'' ''public health investigation,'' and ''public health intervention,'' means population-level activities to prevent disease and promote health of populations. 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.[28]

This definition is narrower than public health activities described in 164.512(b). It is not clear from this definition or the preamble whether the Department meant to exclude activities of public health that are not population-based but focus on the individual in the interest of protecting public health. Public health activities can and must include administrative investigation or proceeding against individuals to control the spread of infectious diseases, including those that can be sexually transmissible such as the Human Immunodeficiency Virus (HIV), Hepatitis A, or Mpox).

The proposed definition of "public health" in NPRM R 160.103 raises concerns as it may be interpreted to require the disclosure of PHI for public health interventions and activities regarding individuals only under 164.512(f)(1)(C) as an "administrative request required by law" when a disease or suspected disease poses a potential threat to public health. This limitation could have detrimental effects on public health agencies' ability to obtain health information for administrative or civil proceedings, such as quarantine or isolation, in cases involving infectious diseases. Administrative investigations play a vital role in addressing these concerns by conducting thorough contact tracing, collecting comprehensive health information, and facilitating necessary testing, treatment, and support services, and many of these activities can be described as "administrative requests required by law" or may involve civil actions such as injunctive action when an individual persists in exposing others to a communicable disease. However, it is not clear that the Department intended to include these types of public health activities in the requirements to make an attestation and the regulation might be strengthened by further clarification.

We recognize that public health activities are a potential source of information for law enforcement investigations into the seeking, obtaining, providing, or facilitating of reproductive health care. Once PHI passes from the covered entity to a public health authority or component of a hybrid public health authority that is not subject to HIPAA, the information no longer is protected by HIPAA. The Secretary should consider options that preserve public health access to reproductive health care information to carry out public health functions and implement public health programs while protecting reproductive health care information from law enforcement access that could undermine access to or receipt of reproductive health care or reproductive health information by public health entities. For example, in

[28] See proposed 160.103, "public health," NPRM, at 23552.

addition to collection of information from health care providers, public health collects information through unsecure and often unencrypted technology that might enable consumers to be tracked regarding reproductive health care; e.g. consumer's access to public health services and information that relates to reproductive health care through QR Codes, Internet interfaces, telephone apps, and text requests. We recommend the Department consider adding additional appropriate protections for the security of PHI when it is disclosed to public health authorities as it prepares a final rule.

*Addressing language usage in definitions*

If the Department maintains a definition of reproductive care, NCVHS recommends that the Department consider the use of appropriate and clear terms in the regulatory text when providing examples of reproductive health care. For instance, the term "termination of pregnancy" is not preferred and can lead to ambiguities regarding the coverage of abortion services.[29] To address this issue, we recommend using more specific and inclusive language that leaves no room for misinterpretation, ensuring that healthcare providers, regulated entities, and patients have a shared understanding of the services encompassed by reproductive health care.

NCVHS have earlier suggested that if the Department adopts a definition of "reproductive health care" in the final rule, it should consider providing illustrative examples of diverse types of reproductive health care in the regulatory text, or, if not in the regulation itself, then more extensive examples in the preamble and guidance documents that will help covered entities interpret the rule. In so doing, the Department should consider using terms that are easily understood, equitable, respectful and culturally appropriate as emphasized in the *Principles of Equitable Communication* published by the Office of the Assistant Secretary for Planning and Evaluation or by CDC in their Health Equity and Health Communication policy.[30] The Principles state that "[i]n all communications, it is important to be mindful of the meanings of words, how they change over time, and the norms of those that use them (individuals, communities, and organizations)." Therefore, NCVHS recommends that the Department consider referring to the Principles of Equitable Communication and incorporating those principles in the further development of the definition and examples of reproductive health care. Using these Principles, or similar ones published by other organizations, as a guide may be the best way forward to build and maintain a respectful, trustworthy, and cultural equity lens in communication.

**Further define de-identified data**

Under 45 CFR 164.512(f)(1), a regulated entity may disclose PHI pursuant to an administrative request, 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

[29] Kaller, S, et al., "Abortion terminology preferences: a cross-sectional survey of people accessing abortion care." 23 BMC WOMEN'S HEALTH 26 (Jan 19, 2023), *available at* https://pubmed.ncbi.nlm.nih.gov/36658525/.
[30]HHS, ASPE, Office of Science and Data Policy, "Principles of Equitable Communication," (September 2022) *available at* principles-of-equitable-communication.pdf (hhs.gov); CDC, Health Equity Guiding Principles for Inclusive Communication (Aug 2022), available at https://www.cdc.gov/healthcommunication/Health_Equity.html.

used.[31] The Department should examine whether the definition of de-identified data as used in this proposed rulemaking is appropriate and should consider the earlier recommendations made by NCVHS in its 2017 letter to the Secretary.[32]

**Section 164.502—Uses and Disclosures of Protected Health Information: General Rules**

The Department should clarify the relationship between attestation and 164.514(h) regarding verification requirements. The HIPAA Rule at 164.514(h)(2)(iii) states that a covered entity may rely, if such reliance is reasonable under the circumstances, on a request made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal and presume that there is authority to disclose. The Department should consider making explicit in the Final Rule that such reliance is not appropriate in the absence of an attestation.

**Redisclosure**

NCVHS suggests the Department consider adding a requirement that an attestation include a statement that the recipient pledges not to redisclose to another party for any of the prohibited purposes named in the attestation. While we understand that the Department cannot regulate use by parties once disclosed, and that a covered entity is unlikely to have the desire or resources to track what happens to PHI once it is disclosed, HHS nevertheless could consider using its regulatory authority to define what types of statements must be in an attestation for a covered entity to make the initial disclosure.

Such a requirement would give notice to the recipient of records of the expectation that records disclosed under an attestation will not be redisclosed for the same prohibited purposes in the attestation. This would create a record that the attesting entity promised not to redisclose at the time it obtained the records, and, if it thereafter does disclose records for one of the prohibited purposes, that it did so improperly. We further recommend the Department consider adding a requirement that a covered entity stop disclosing records to any entity that is discovered or known by the covered entity to have made a secondary disclosure in conflict with its attestation. Access to PHI should carry with it the expectation of durable protection as that data is shared or utilized by others.

**Updates to the Notice of Privacy Practices.**

Since the proposed rule will require updates to the Notice of Privacy Practices (NPP) in addition to the updates planned for the 42 CFR Part 2 proposed rule[33], NCVHS recommends that the Department consider carrying out these proposed changes concurrently. This will provide less burden to the covered entities since they will not have to make two separate changes to their NPP.

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[31] 45 CFR 160.512(f)(1).

[32] Recommendations on De-identification of Protected Health Information under HIPAA https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2017-Ltr-Privacy-DeIdentification-Feb-23-Final-w-sig.pdf

[33] 87 FR 74216

We suggest the Department consider further modifying the rules regarding NPPs to require, in plain language, an explanation of the Privacy Rule's limitations. Individuals should understand that once PHI is disclosed for a permissible purpose to an entity other than a covered entity, the Privacy Rule protections would no longer apply. This is very important for individuals to understand, particularly if they choose to release their information to non-covered entities like health apps or other healthcare adjacent entities.

The proposed language of the NPRM requires the NPP to be updated with a description and one example of the types of uses and disclosures prohibited under the new section protecting reproductive health. Given the potential for states where reproductive health care is curtailed to pass new laws restricting access to reproductive health care, a state could try to dictate what the NPP should say with the intention purposefully confuse patients about their rights.

NCVHS supports the Department's public statements of commitment to the availability of accurate reproductive health information.[34] To ensure continued access to accurate reproductive health information, NCVHS recommends the Department consider being more prescriptive than in the proposal.

For example, the Department might phrase such language for the NPP as follows:

*We will not use or disclose your protected health information (PHI):*

- *for criminal, civil, or administrative investigation into or against any person seeking, providing or facilitating reproductive health care, or to identify any person seeking, providing, or facilitating reproductive health care.*
- *We will not disclose protected health information to a law enforcement entity inquiring about the provision of (reproductive) healthcare to you or by your healthcare provider if the purpose is to bring legal action against you or any other person merely for seeking, obtaining, providing or facilitating your health care.*

In general, we recommend that the Department consider specifying language for the Notice of Privacy Practices in plain language that is clear and understandable to all patients.

**Authorities**

To effectuate protections for access to reproductive and other health care, the Department should use all available authorities at its disposal. While this rulemaking is based on authorities in HIPAA, the Department has other regulatory authorities other than those within HIPAA itself. NCVHS recommends that the Department consider exercising those authorities to the greatest extent practicable to protect access to reproductive and other health care.

[34] See, e.g., HHS, Know Your Rights: Reproductive Health Care (last updated June 25, 2022), available at https://www.hhs.gov/about/news/2022/06/25/know-your-rights-reproductive-health-care.html.

For example, whenever the federal government gives financial support to an activity, the recipients of those funds may be subject to controls imposed through the program. HHS also has authority to flesh out general statutory provisions and establish requirements for many different programs that touch on the provision or education about reproductive health care. Therefore, HHS could impose regulations, either separate from the HIPAA regulations, or through the current regulatory process with the support of additional authority in the final rule. These might be based, for example, on Medicare conditions of participation, terms and conditions for discretionary grants, contract conditions, cooperative agreements, voluntary programs, or the use of other existing authorities.

We note that the Department is considering extending provisions of HIPAA rules to non-HIPAA covered entities through contractual means, most recently and most broadly in the 21st Century Cures Act Trusted Exchange Framework and Common Agreement (TEFCA). Health information access or exchange through any TEFCA participating entity is expected to encompass most sharing of PHI among individuals, healthcare and non-healthcare entities alike (including HIPAA and non-HIPAA covered entities) across the U.S. as it becomes fully implemented nationwide. Because TEFCA participating entities will hold information potentially related to reproductive health care, we recommend the Department consider publishing explicit guidance regarding

**Topics that are not addressed in the rule**

NCVHS recommends that the Department consider addressing the use of telehealth and telemedicine[35] to access reproductive health care in cases where legal variations exist among states.

*Telemedicine*

Based on the language in the proposed rule, is not clear whether an attestation would be required in the following situations:

[35] Multiple sources define these terms differently. See, e.g. Health Resources and Services Administration, Office for the Advancement of Telehealth "What is Telehealth," (last updated Mar. 2022)(defining telehealth as "the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health") *available at* https://www.hrsa.gov/rural-health/topics/telehealth/what-is-telehealth; Centers for Medicare and Medicaid Services, "Telehealth" (no date)(describing telehealth as "the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance" and noting that "At one time, telehealth in Medicaid had been referred to as telemedicine."), *available at* https://www.medicaid.gov/medicaid/benefits/telehealth/index.html; ONC, HealthIT.gov, "What is Telehealth" (no date)( describing Telehealth is different from telemedicine because it refers to a *broader scope of remote healthcare services* than telemedicine. While telemedicine refers specifically to remote clinical services, telehealth can refer to remote non-clinical services, such as provider training, administrative meetings, and continuing medical education, in addition to clinical services), *available at* https://www.healthit.gov/faq/what-telehealth; See also Majerowicz, Anita; Tracy, Susan. "Telemedicine: Bridging Gaps in Healthcare Delivery" JOURNAL OF AHIMA 81, no.5 (May 2010): 52-53,56.
See https://library.ahima.org/doc?oid=100028

1. A patient residing in a state where care is illegal seeks reproductive health care from a provider in a state where it is legal. The patient may be at risk of a law enforcement request for records if the care is not legal in the state where the investigation is occurring, and the records could be used against the patient merely for obtaining care from a legal source in another state.
2. A provider located in a state where care is illegal but who has a license to provide care, via telehealth platform, to patients residing in states where it is legal may be at risk because the patient's records could be obtained in their state to open an investigation merely for providing care to a patient in another state where the care is legal.

Moreover, a state might choose to prosecute as "aiding and abetting" third parties in these types of transactions, such as the providers of the telehealth platform through which the care was provided.

Telehealth is another example of the complexities of today's health care system in which transactions of care and of payment through insurance are conducted across state lines. This provides further support for the position that if the rule were to require an attestation of parties subject to 164.512(e), (f), and (g) for all requests for medical records, it would do a better job of protecting patients, providers, and others who facilitate reproductive health care while reducing the burden on covered entities.

Even if HHS does not choose to adopt an approach requiring an attestation for all such requests in the final rule, it would be beneficial to provide clarification about how the new provisions are intended to be implemented and examples related to telemedicine. Without further clarification and examples, the application of the rule will be very confusing in an environment where some types of reproductive health care via telehealth are protected in one state and a felony in a sister state.[36]

*Telehealth*

Compared to telemedicine, telehealth encompasses a broader range of technologies that may or may not be covered by HIPAA. This includes digital health apps, sensors and wearables, and other health tracking tools that are used by individuals independent of provider advice. Health data collected by these technologies can be used for purposes external to the formal health care system. Beyond HIPAA, HHS should consider collaboration with other federal agencies interested in protecting consumer and patient privacy. Addressing privacy violations by individual companies is insufficient for accountability across the digital health sector.

Amid escalating state-level restrictions on access to reproductive health care, concerns have arisen about the potential risks associated with the interoperability and information blocking rules of CMS[37]

[36] *See* Farah Yousry, "Telemedicine abortions just got more complicated for health providers," National Public Radio (Sept. 22, 2022) (describing specific cases of reproductive health care provided via telehealth), *available at* https://www.npr.org/sections/health-shots/2022/09/26/1124360971/telemedicine-abortion-medication-ban.

[37] Centers for Medicare and Medicaid Services, "Final Rule: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, and Health Care Providers," 85 Fed. Reg. 25510 (May 1, 2020).

and ONC.[38] These rules encourage the use of Application Programming Interfaces (APIs) to promote the development of applications that would allow individuals to download their health data onto personal devices. We applaud the work of CMS and ONC to expand patient access to their own records, and agree with their core purposes as stated in the ONC rule, "to promote interoperability and to support care coordination, patient engagement, and health care quality improvement initiatives."[39] We agree that advancing health IT that promotes and supports patient care when and where it is needed should continue to be a primary goal of these programs. However, the legal environment has changed significantly since the rules were promulgated, and the Department should consider addressing the increased privacy risks to patients as a result.

The American Medical Association (AMA)[40] and others warned about the significant unintended consequences, particularly for patients who opt to transfer their records to a third party or to their own phones and discover that their data was used in ways they did not anticipate or understand. This concern is particularly relevant in states where some types of reproductive health care had become illegal. They appreciated CMS' acknowledgment of "unscrupulous actors" who could use apps to profit from an individual's information in ways that the individual did not authorize or understand, noting that "stories and studies abound about how smartphone apps share sensitive health information with third parties, often without the knowledge of an individual. They noted that "most patients will not be aware of who has access to their medical information, how and why they received it, and how it is being used (for example, an app may collect or use information for its own purposes, such as an insurer using health information to limit/exclude coverage for certain services, or may sell information to clients."[41] Those risks continue in the post-Dobbs era,[42] but are more acute for patients who seek or obtain reproductive health care.

At the time of the CMS and ONC rulemakings in May 2020, the Department considered it the patient's responsibility to choose their applications wisely and relied on public education to mitigate any possible harms. The Department also relied on the FTC's jurisdiction over these consumer matters. Given the new legal reality, NCVHS suggests that the Department consider taking additional steps to protect patients and their providers, rather than to leaving the burden on patients and the enforcement solely to the FTC.

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[38] Office of the National Coordinator for Health IT, "Final Rule: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," 85 Fed. Reg. 25642 (May 1, 2020).
[39] Id. at 25646.
[40] Letter from James Madara, Executive VP and CEO, Am. Med.Assoc., to Hon. Seema Verma, Administrator, CMS, May 31, 2019 (commenting on proposed rule docket CMS-9115-P).
[41] See, e.g., Drew Harwell, Washington Post, *Is your pregnancy app sharing your intimate data with your boss?* (April 10, 2019), *available at* https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?utm_term=.3b82122fec27.
[42] See, e.g., FTC, Press Release: "FTC Sues Kochava for Selling Data that Tracks People at Reproductive Health Clinics, Places of Worship, and Other Sensitive Locations: Agency Alleges that Kochava's Geolocation Data from Hundreds of Millions of Mobile Devices Can Be Used to Identify People and Trace Their Movements" (Aug. 22, 2022), *available at* https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-sues-kochava-selling-data-tracks-people-reproductive-health-clinics-places-worship-other

NCVHS fully supports the patients' right to access their own records easily, inexpensively, and seamlessly. However, the Department should consider further measures to guard against potential unintended consequences of interoperability, especially in a mostly unregulated environment. As patients more frequently use these apps promoted by the Department's interoperability rules, the risk of their information being used or accessed by state and local law enforcement for investigations increases. To promote trust and protect privacy rights, we encourage the Department to consider further action to protect the data in those applications.

**Workforce**

There is growing concern within the medical community, with medical students and residents contemplating whether to apply to programs in states where abortion training is illegal. The conflict between state abortion bans and accreditation requirements puts residency programs in a challenging position. Providing abortion training could lead to prosecution, but not offering it risks losing accreditation. The limited exposure to these life-saving procedures hinders the training process and hampers the development of essential skills and expertise in reproductive health care. Predictions suggest that over 43% of OB-GYN residents will lack abortion training in 21 states.[43] The reduction in OB-GYN residents and specialists in states with restrictive laws will exacerbate existing maternal health disparities due to the emergence of maternity care deserts.

[43] Vinekar, Kavita, et al. Projected Implications of Overturning Roe v Wade on Abortion Training in U.S. Obstetrics and Gynecology Residency Programs. 140 OBSTETRICS & GYNECOLOGY 2, at146-49 (Aug. 2022).