June 15, 2023

Director Melanie Fontes Rainer
Office for Civil Rights
U.S. Department of Health and Human Services
Attention: HIPAA and Reproductive Health Care Privacy NPRM
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201.

RE: Notice of Proposed Rulemaking: HIPAA Privacy Rule to Support Reproductive Health Care Privacy (RIN Number 0945–AA20)

Dear Director Fontes Rainer:

The Confidentiality Coalition appreciates the opportunity to comment on the Notice of Proposed Rulemaking to modify the HIPAA Privacy Rule to support reproductive health care privacy published by the Department of Health and Human Services (HHS or Department) Office for Civil Rights (OCR) in the Federal Register on April 17, 2023 (proposed rule).[1]

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, and others, committed to advancing effective health information privacy and security protections. Our mission is to advocate policies and practices that safeguard the privacy and security of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

I. General Comments

The Confidentiality Coalition strongly supports the Department's stated goal of preserving trust in the health care system by ensuring the proper balance between individual privacy and legitimate state prerogatives. We agree that this trust, and particularly the trust relationship between patient and provider, is the underpinning of

[1] 88 Fed. Reg. at 23506 (April 17, 2023).

the health care system, and any actions which improperly impinge on this relationship could lead to a reduction in the quality of and access to care. We also believe it is important for health care providers to have access to a patient's complete medical record to be able to take a holistic approach to care, which results in a better patient experience and better health outcomes. A single national privacy law at the federal level that provides robust protection for all health data allows for the integrity of health records and is more workable than navigating the numerous, varying state privacy laws that are proliferating in its absence.

We appreciate the Department's attempt to limit the burden on covered entities and business associates (collectively, regulated entities) by creating a purpose-based prohibition, consistent with the existing approach in the HIPAA Privacy Rule. However, we are concerned that, as proposed, the rule would require regulated entities to make legal determinations that even courts of law find challenging to make, despite having far more expertise and information with which to do so. Moreover, a regulated entity would face potentially dire consequences if a court or the Department disagreed with its determination, no matter how careful or considered that determination was. Not only does this put regulated entities in the untenable position of potentially violating the HIPAA Privacy Rule if they decide one way and state law (and potentially other federal law, such as the information blocking rules) if they decide the other, but critically, this will not achieve the Department's goal of maintaining trust in the health care system. Instead, requiring regulated entities to wade into the legalities of seeking or providing certain types of care would have the opposite effect, undermining patients' relationships with their health care providers and plans, putting those entities in the middle of, and effectively making them arbiters of, highly sensitive legal disputes. In addition, given the proposed attestation requirement for certain disclosures of protected health information (PHI) "potentially related to reproductive health care," regulated entities would still be required to categorize and distinguish between different types of PHI, a near impossible task given the sweeping definition of "reproductive health care", and contrary to the Department's stated intent to avoid this unduly burdensome approach by creating an ostensibly purpose-based prohibition.

Considering the above concerns, we recommend that the Department consider alternatives to its proposed approach. One alternative is to strengthen the current requirements for the disclosure of any PHI in legal or criminal proceedings or to law enforcement so that these are permitted only pursuant to a court order or grand jury subpoena. The Department states that it has always intended the current requirement to allow disclosures pursuant to administrative requests only if these are enforceable by law, and so is taking the opportunity to clarify this.[2] By clarifying the requirement, HHS would eliminate some of the confusion experienced by patients and providers alluded to

[2] See 88 Fed. Reg. at 23858 ("The examples of administrative requests provided in the existing regulatory text include only those requests that are enforceable in a court of law, and the catchall ''or similar process authorized by law'' similarly is intended to include only requests that, by law, require a response. This interpretation is consistent with the Privacy Rule's definition of ''required by law,''…. However, the Department has become aware that some regulated entities may be interpreting this provision in a manner that is inconsistent with the Department's intent. Therefore, the Department is taking this opportunity to clarify the types of administrative processes that this provision was intended to address").

in the preamble discussion of this alternative, and give them the assurance that their PHI will only be disclosed if a court requires it or it is pursuant to legal process that is enforceable by a court of law. However, HHS could go even further, and allow disclosure of any PHI in legal or administrative proceedings or pursuant to a law enforcement request only if the request is accompanied by a court order, unless authorized by the individual. This would go a considerable way to address the Department's concern that the current legal and regulatory environment is "diminishing the ability of individuals to receive medically appropriate health care that remains legal under the circumstances in which it is provided" since a court would be in the best position to evaluate whether the care is legal under the circumstances, and so whether the mandated disclosure justified.

Alternatively, the Department could have the party seeking the records have to make a prima facie showing to a court that the reproductive health care services being investigated are unlawful in the circumstances. That way, courts, rather than health care entities, are making the determinations about the lawfulness of the reproductive health services, and so whether a disclosure is prohibited. Health care entities should focus on what they do best, namely, the delivery of health care, and the requestor tasked with making a prima facie showing regarding the unlawfulness of the activities about which the PHI is sought. Not only are courts better suited and equipped to make these types of determinations than are health care organizations, but this is the only way the Department would achieve its primary goal of maintaining trust in the health care system, a prerequisite for quality health care.

Finally, HHS could consider requiring HIPAA authorizations for disclosures of any PHI for purposes permitted under 45 CFR 164.512(a)-(g) unless the regulated entity receives a written attestation under penalty of perjury that the PHI is not being requested for a prohibited purpose. Regulated entities should be permitted to rely on such attestations without requiring further investigation or legal determinations. This alternative would retain the appropriate balance between protecting individual privacy while allowing access for purposes outside of treatment, payment, or health care operations (TPO) where there is a legitimate public interest as attested to by the requesting party. However, this approach still imposes a significant burden on regulated entities to determine the purpose of a request and that the attestation meets all regulatory requirements, and requires that the requestor be acting in good faith and qualified to make the determinations necessary to provide the attestation.

All these alternatives would be preferable to the approach in the proposed rule in that they would provide more robust protections for all PHI, would not require a parsing of PHI to determine whether it potentially relates to reproductive health, and avoid having regulated entities make determinations regarding the legality of certain reproductive health services, a role for which they are wholly unsuited.

II. Specific Comments

Below are our specific comments on the proposed modifications to the HIPAA Privacy Rule.

A. Section 160.103—Definitions

1. Adding a Definition of "Reproductive Health Care"

The Department proposes a definition of "reproductive health care" that it states is intended to be "interpreted broadly to capture all health care that could be furnished to address reproductive health, including the provision of supplies such as medications and devices, whether prescription or over-the-counter (OTC)." While the Department references the definition of "reproductive health services" adopted by Congress in 18 U.S.C. 248(e)(5) -- which is limited to services provided in a hospital, physician's office, or other facility -- its proposed definition is much broader, not being limited to care provided by health care providers or even in a health care setting. The Department adds that it is not proposing a definition of the term "reproductive health," the operative term in the definition of "reproductive health care," although it recognizes that this may be helpful to stakeholders.

We recommend that the Department reconsider the proposed definition of "reproductive health care," both as to its substance and purpose. As written, regulated entities would in most cases not have the means to determine whether the PHI in question relates to reproductive health care. The examples provided by the Department make this clear, since even a high blood pressure reading or high glucose level, which on their face are not related to reproductive health care, indeed may be. There are many other examples that could be provided, and a vast array of services and supplies that could be implicated. Looking at drugs alone, there are over three hundred drugs prescribed for contraception and prenatal care. This does not even consider OTC products or supplies, which raise even more significant challenges, since the purchaser may not be, and often is not, the patient. Under the proposed definition, regulated entities would have no choice but to view all PHI as potentially related to reproductive health care. Therefore, the proposed new requirements would, as a practical matter, apply to all PHI.

If the Department proceeds with the proposed approach of having regulated entities make legal judgments about the lawfulness of care -- an approach which we strongly oppose -- at a minimum it should limit this to PHI: (1) that clearly and on its face relates to the voluntary termination of pregnancy, (2) where it is clear that the reproductive health services were provided to the individual whose PHI is being requested and (3) where a prima facie showing can be made from the PHI alone that the reproductive health care services were potentially unlawful in the circumstances. Thus, PHI related to treatment of gestational diabetes or preeclampsia or any diseases, or miscarriages or fertility treatments, or PHI of individuals no longer of reproductive age or dealing with the male reproductive system, should all be out of scope. So should OTC products and supplies, as well as any PHI where it is not clear on its face where the potentially unlawful activities occurred since lawfulness will differ from state to state. As such, medications and supplies should be out of scope unless dispensed pursuant to a prescription for purposes of the voluntary termination of pregnancy under circumstances where that was potentially unlawful.

Even narrowed in this manner, the definition would involve regulated entities making legal determinations which they are in no position to, nor should they be required to, make. To address this, and as discussed further below, the Department could require that any request for PHI be required to specify (1) the exact records being requested, (2) a statement whether or not the primary purpose is to impose liability for seeking, facilitating or providing reproductive health care services, and (3) if this is the primary purpose, why the prohibition does not apply (i.e., why the requestor believes the reproductive health services were unlawful in the circumstances).

***Recommendation: HHS should adopt a much narrower definition of "reproductive health care" PHI for purposes of the proposed prohibition and attestation, limiting it to PHI that clearly and on its face relates to the voluntary termination of pregnancy services provided to the individual whose PHI is being requested, and* under circumstances where those services were potentially unlawful.**

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

1. Adding a New Category of Prohibited Uses and Disclosures of PHI

The proposed rule would establish a new category of prohibited uses and disclosures of PHI, namely, where requested in legal or administrative proceedings or investigations related to seeking, providing, or facilitating the provision of reproductive health care or identifying a person involved in seeking, providing, or facilitating the provision of reproductive health care that is lawful in the circumstances. The Department states that this prohibition is narrowly tailored so as to limit harmful uses and disclosures and not interfere with legitimate state prerogatives.

We appreciate the Department's efforts to narrowly tailor the prohibition and base it on the purpose for the request rather than the type of PHI being requested. However, while the situations in which the prohibition may ultimately be triggered may be relatively few, the broad definition of reproductive health care would require regulated entities to make a legal determination in nearly all, if not all, cases in which PHI is requested in connection with legal or administrative proceedings or law enforcement investigations. Many regulated entities receive thousands of law enforcement administrative requests a year, with most simply providing the individual's name and a date range for the records requested. In addition, unlike the existing purpose-based uses and disclosures of PHI in the Privacy Rule which require a regulated entity to determine only that the PHI is sought for a legal proceeding or law enforcement investigation, this prohibition would require regulated entities to go significantly further, and determine the purpose of the proceeding or investigation and whether the conduct or activity being investigated is "lawful in the circumstances." Regulated entities would in most cases not have the information needed to make such a determination and so would need to ask patients and their providers for additional information (e.g., about the purpose for which certain health care drugs, services and supplies were obtained where that activity occurred if

different from the place where the PHI records in question were generated, and the circumstances under which it occurred).

These types of inquiries would have a chilling effect on individuals' willingness to seek care, possibly even greater than do the current disclosures the Department seeks to prohibit, and so would have the opposite effect of that intended by the proposed rule. Even after having gathered all the information available, regulated entities still may not be able to clearly determine whether the reproductive care was lawful in the circumstances. Given the grave ramifications for a potentially "wrong" decision, we ask that if HHS proceeds with the prohibition, it explains clearly what regulated entity would be expected to do when the lawfulness of the care cannot be clearly determined based on the information held by the regulated entity. Clear instructions to follow and examples of how to implement the prohibition in various scenarios where the lawfulness of the reproductive health care is not clear or cannot be ascertained from the PHI would help regulated entities implement the prohibition and ensure more consistent compliance. Regulated entities should not be subject to any penalties or enforcement action if their determination is ultimately found to be wrong or HHS disagrees with it, as long as their determination was made in good faith.

The only way to avoid the chilling effect of these types of legal inquiries is to take health care entities out of the business of having to judge the lawfulness of health care decisions made by their patients and other health care providers. As mentioned above, this could be done by, for example, requiring that regulated entities not disclose any PHI in connection with a legal or administrative proceeding or law enforcement investigation unless furnished with a court order or determination by a court that the PHI is not requested for a prohibited purpose. Courts have the expertise and fact-gathering mechanisms to make this type of determination and can do so without eroding the patient-provider relationship or trust in the health care system. Alternatives would be to require that the disclosure of any PHI pursuant to legal or administrative proceedings or a law enforcement investigation be accompanied by a HIPAA authorization or written attestation that, on its face, contains the required statements. Requiring requestors to provide a written attestation would ensure that certain legitimate inquiries by law enforcement or in legal or administrative proceedings that further the common good, such as to investigate potential health care fraud, could proceed. However, as noted above, this approach has some drawbacks as compared to an approach that relies on a court to make the required legal determinations.

The proposed prohibitions would also place regulated entities in an unprecedented precarious legal position, potentially "damned if they do and damned if they don't." Specifically, if a regulated entity makes the determination not to comply with a court order to disclose PHI because it believes the order relates to the provision of reproductive health care that was lawful in the circumstances, it could be found in contempt of court if a court disagrees with its determination or in violation of other federal law, such as the information blocking rules, if the Department disagrees with its determination. However, if it makes the opposite determination and complies with the court order, it could be found to be in violation of the Privacy Rule, required to provide

breach notifications and subject to civil monetary penalties if the Department disagrees with that determination. No organization trying to comply with the law should be placed in such an invidious position, least of all health organizations that are being forced to make legal determinations that even courts of law designed for this purpose would struggle to make.

In addition to the above issues, the proposal assumes that regulated entities will know where the potentially unlawful activity occurred based on the PHI requested. Given the breadth of the definition of reproductive health care, this is unlikely to be the case in most situations. For example, in what state should regulated entities consider telehealth and /or mail-order pharmacy prescriptions as being provided? Simply because a patient is treated for high blood pressure or diabetes or even provided prenatal care or medications in one location (none of which health care is potentially unlawful under any circumstances) does not mean that the potentially unlawful activities occurred in the same location. This same concern applies with respect to the written attestation discussed further below, where HHS states explicitly that regulated entities, rather than the requester, will have the information necessary to make the required legal determination. While this may be true in a small subset of cases, it will not be the case for the vast majority of requests, particularly with respect to PHI for ancillary care, such as diagnostic tests, laboratory tests, medications, and supplies.

Recommendation: HHS should not require regulated entities to determine the lawfulness of reproductive health services. Not only are these entities ill-equipped to make these types of determinations, but doing so will harm their relationship with their patients and members. It will also subject them to serious legal jeopardy, whatever they decide.

2. Creating a Category of "Highly Sensitive" PHI

The Department asks several questions regarding the creation of a category of "highly sensitive" PHI that is to be potentially subject to additional restrictions. We believe that the Department's deliberate decision in the 2000 Privacy Rule not to create different categories of PHI was the correct one, and the reasons for not doing so are still valid, if not more so, today. As the Department made clear in the 2000 Privacy Rule, all PHI is, by its nature, sensitive and deserving of robust protection, which the Privacy Rule amply provides. Trying to distinguish between the sensitivity of different types of PHI not only requires notoriously difficult subjective determinations, but as with the Department's effective requirement to determine what PHI is "potentially related to reproductive health care," fraught with practical challenges. PHI records, particularly for drugs and supplies, but also for many other items and services, often do not indicate on their face the underlying purpose for which they were obtained. In addition, as the Department itself acknowledges, even if these conceptual distinctions could be successfully made, clinical record systems and health claims systems do not currently have the technical capability to differentiate between different categories of PHI or to segment records.

Finally, segmenting certain types of PHI and subjecting these records to additional restrictions runs counter to efforts to improve the quality of care and care coordination.

The Department has proposed several rules, through the Office of the National Coordinator of Health Information Technology (ONC), the Centers for Medicare and Medicaid Services (CMS), the Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA), that would move health organizations towards greater sharing and integration of electronic health records. This would allow health organizations to have a more complete and holistic picture of their patients' overall health. Creating new categories of PHI for the purpose of imposing greater restrictions on their use and disclosure, while well-intentioned, would be a step backwards and have a detrimental effect on the quality of care.

We agree with the Department that it is important to retain the right balance between appropriately facilitating access to, and integration of, records for TPO purposes of regulated entities, and limiting access to non-regulated entities that seek these records for other purposes, particularly when such entities are not subject to the same or similar constraints and safeguards as are regulated entities. The Department alludes to this in its question regarding the possibility that third parties might seek to circumvent the prohibition by coercing individuals to exercise their right to direct a covered entity to transmit to a third party an electronic copy of their PHI in an EHR. As we have previously stated in our comments on the proposed modifications to the Privacy Rule for care coordination, third parties are already abusing this right by using it to obtain records for non-health purposes at little or no cost, and without HIPAA authorizations that would at least put the individual on notice as to what records are being shared, with whom and for what purpose. Some third parties even sell the PHI, often for purposes adverse to patients' interests, including some of the purposes about which the Department raises concerns in the proposed rule.

Rather than impose the obligation on regulated entities to be the gatekeepers, with potentially dire consequences whether they provide access or refuse to do so, we recommend that the Department apply a consistent approach of limiting third party access to situations where the third party provides an attestation (discussed further below) or a patient authorization. This would include disclosures pursuant to a patient's third-party directive, in which case regulated entities should be permitted to charge a reasonable fee to the third party for the records. These measures would reduce the number of questionable directives that regulated entities receive and would further the Department's goal of facilitating the sharing of PHI for TPO purposes, while ensuring that appropriate safeguards are in place for disclosures for other purposes.

<u>Recommendations</u>:

- ***HHS should not create a new category of "highly sensitive" PHI for purposes of imposing additional restrictions on its use and disclosure. This would adversely impact the quality of care and run counter to HHS' efforts to improve care coordination and interoperability.***
- ***HHS should instead take steps to limit the inappropriate access to PHI for non-TPO purposes, such as by requiring third party requests to be accompanied by attestations or HIPAA authorizations.***

C. Section 164.509—Uses and Disclosures for Which an Attestation Is Required (Proposed Heading)

The Department proposes to add a requirement to obtain an attestation from the person requesting the use and disclosure of PHI that potentially relates to reproductive health care as a condition for certain permitted uses and disclosures. It notes that this would help effectuate compliance with the new prohibitions because regulated entities would have difficulty distinguishing between permitted and prohibited uses and disclosures.

We agree that the written attestations could assist regulated entities with compliance, but only if regulated entities are permitted to rely on facially valid attestations. It would defeat the purpose of requiring such an attestation if regulated entities would still need to determine for themselves whether the reproductive health care services in question are lawful. The Department states that it is not objectively reasonable for regulated entities to rely on representations of requesters on this issue because the regulated entity, and not the requester, has the information about the provision of such care that is necessary to make this determination. However, it is highly unlikely that regulated entities have the information necessary to make such a determination, even if they themselves are providing the care that is in dispute[3]. In addition, even if they manage to obtain all the necessary information, this once again puts regulated entities in the middle of disputes regarding the legality of health care services. Regulated entities should be permitted to rely in good faith on the requestor's attestation that PHI is not requested for a prohibited purpose.

We are also concerned with the requirement that, if in the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity discovers information reasonably showing that the representations in the attestation were materially false, the covered entity must cease the use or disclosure. This assumes a level of internal monitoring and communication that is not practical or operationally feasible for regulated entities, nor is it clear what responsibility this imposes on a regulated entity that may learn of new information that could potentially be relevant to the correctness of attestations on which it relied to disclose PHI. For example, if there is a court decision in a state that determines that certain reproductive services previously held to be unlawful are now lawful, would a regulated entity be expected to review the attestations it received in the past and now reassess whether they are affected? Or would the requestor be required to attest that if any of the facts change such that the attestation is no longer valid, the requestor will notify the regulated entity? In either case, if the Department proceeds with the attestation requirement, it should make clear in the final rule what the responsibilities of the regulated entity are in these types of situations.

[3] For example, a pharmacy that is asked to provide a patient's prescription records would in most cases have no way of knowing whether some of the medications or supplies were related to an unlawful procedure. Similarly, lab results, ultrasounds and physical examinations could all be related to an unlawful procedure without the providers themselves being involved in, or knowing about, the procedure.

HHS asks whether it should provide a model form that can be used for the written attestation. We strongly support this and ask that it include multiple examples of acceptable descriptions of classes of individuals whose PHI is requested and recipients, so that regulated entities have the assurance that the document meets all the specified requirements. We also ask that rather than a one-time use, the attestation be valid for a stated period in the same way as a HIPAA authorization. Also, if the Department retains the prohibition on compound attestations, we ask that the regulatory text make clear exactly what constitutes "combining" an attestation with another document, including whether this means that the attestation must have a separate signature or checkbox if included visually separately on the same document. Finally, the attestation should include statements explaining the specific purpose for which the PHI is being requested, confirmation the requested PHI is the minimum necessary for the stated purpose, and that the PHI will not be used or disclosed for prohibited purposes. Regulated entities should be permitted to rely on such attestations for purposes of the meeting the minimum necessary standard.

We are also concerned that it would be difficult in most cases for regulated entities to determine when an attestation is required. Even if the Department implements a narrower definition of reproductive health care, regulated entities would likely not have sufficient information to determine whether the PHI "potentially relates" to reproductive health care services. They also may not be able to determine under which HIPAA permission the request falls. Rather than place regulated entities in the position of having to decide when an attestation is required, it would be clearer and simpler to require that an attestation or HIPAA authorization accompany any request for any PHI for a legal or administrative proceeding or law enforcement investigation, or even for any non-TPO purpose. That way regulated entities are not put at odds with requesting entities that believe they are not required to provide the attestation and refuse to do so, or with patients and members for not obtaining an attestation or authorization before disclosing their PHI for non-TPO purposes.

HHS should also provide clarity in any final rule on the interaction of the attestation requirement with other Privacy Rule provisions, such as authorizations. For example, if a patient chooses to authorize a disclosure for a health oversight purpose or for a law enforcement investigation, it is not clear whether the regulated entity would be permitted to disclose the PHI without an attestation. We recommend that regulated entities be permitted to accept HIPAA authorizations to disclose the PHI in circumstances that would otherwise require an attestation, and as an alternative to the attestation requirements. We understand HHS' concern about potential coercive tactics by law enforcement or others, but believe that these concerns can be mitigated. For example, in the case of disclosure of PHI that directly relates to termination of pregnancy services, the authorization could be required to include a prominent statement warning the individual that their PHI could be used in legal or administrative proceedings or investigations against them or their health care provider. To reduce administrative burden, regulated entities should also be permitted to accept other documentation in lieu of an attestation in the case of requests from certain, identified government entities or regularly requested data requests. The Department should give examples of the

types of documentation that would be acceptable for this purpose, either in the final rule itself or in the preamble or associated guidance for implementing the final rule.

Recommendations:

- ***Regulated entities should be permitted to rely on attestations that include the required elements without having to look behind the statements to determine whether they are materially false or that the health care was lawful in the circumstances.***
- ***All requests for PHI for legal or administrative proceedings or law enforcement investigations should have to be accompanied by either a written attestation of a valid HIPAA authorization or, in the case of requests by certain government agencies, based on alternative documentation, examples of which should be provided by HHS.***

D. Section 164.520—Notice of Privacy Practices for Protected Health Information

We support including language in the Notice of Privacy Practices (NPP) explaining the proposed prohibition and attestation requirements. We also support adding a statement that when PHI is disclosed for a permitted purpose to an entity other than a covered entity (e.g., disclosed to a noncovered health care provider for treatment purposes), the recipient of the PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply. We ask that the Department provide model language for all the proposed revisions, and that it allows covered entities to use up their existing supplies of paper NPPs before being required to provide paper copies of the updated version.

Recommendations:

- ***HHS should provide model language for the updates that would be required for the NPP.***
- ***HHS should allow covered entities to use up their stock of existing paper NPPs before being required to distribute the updated version.***

E. Compliance Date and Implementation

The Department proposes to apply the standard compliance date of 180 days after the effective date of a final rule, stating that it does not believe that the proposed rule would pose unique implementation challenges that would justify an extended compliance period. As our comments have pointed out, there are many difficult and operationally challenging requirements involved in implementing the proposed rule. Not only will regulated entities need to develop processes, policies, and procedures for handling requests potentially subject to the prohibition, but they will be required to develop written attestations, revise their notices of privacy practices, and potentially amend business associate agreements. Depending on the requirements of the final rule, they could also need to hire the legal and investigational resources necessary to make the required legal determinations. This will in turn require keeping up with the law on reproductive health. Many regulated entities will need to do this across multiple jurisdictions.

Given the significant operational impact of the changes, we ask that regulated entities be allowed a minimum of 12 months to come into compliance. In addition, given the profoundly serious potential consequences for incorrect determinations, we ask that the proposed rule incorporate a good faith standard similar to that for other disclosures under 45 CFR 164.512, such as for crimes on the premises of a covered entity or to avert a serious threat to health or safety. This will provide at least some protection to regulated entities that are forced to make legal determinations with which the Department may ultimately disagree.

Recommendations:

- ***HHS should allow regulated entities at least 12 months after the effective date of a final rule to come into compliance with its requirements.***
- ***HHS should incorporate a good faith standard similar to that for certain other types of uses and disclosures, such as those to avert a serious threat to health or safety, for disclosures subject to the prohibition and attestation requirements.***

F. Business Associates

The proposed rule would apply the prohibition to both covered entities and business associates, but the attestation requirement only to covered entities. We ask that the Department clarify the reason for this distinction, and also clearly explain the role and responsibility of business associates under both the prohibition and the attestation.

Specifically, we ask for clarification whether the proposed rule's requirements would apply to business associates in the same way as they would apply to covered entities in situations where the business associate receives a request for PHI directed to the business associate itself. If so, HHS should clarify the responsibility of each party in this situation, particularly if the covered entity disagrees with the business associate's determination as to the lawfulness of the reproductive health care services in question, and even though it is the business associate that is "required by law" to make the disclosure. We also ask that HHS clarify whether it would be necessary to amend business associate agreements to address the requirements of the proposed rule and, if so, what changes would be required.

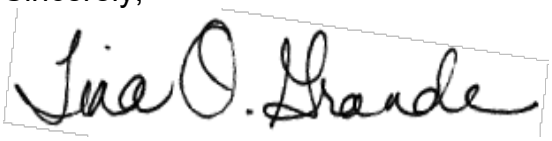
Recommendations:

- ***HHS should clarify the respective roles and responsibilities of covered entities and business associates to comply with the proposed prohibition and attestation requirements.***
- ***HHS should clarify whether it would be necessary to amend business associate agreements if the proposed rule is finalized and, if so, what revisions would be required to these agreements.***

Thank you for your consideration of our comments. We appreciate the Department's efforts to protect the confidentiality and integrity of the patient-provider relationship, to maintain patient trust in the health care system, and to ensure that patient records are accessed only for health care or legitimate and broadly accepted public policy purposes.

Please do not hesitate to contact me at tgrande@hlc.org or 202-449-3433 if you have any questions.

Sincerely,



Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council