April 2023 Proposed Amendments to the Privacy Rule to Support Reproductive Health Care Privacy: OCR Requests for Comment

IV.A. Section 160.103—Definitions

4. The Department requests comment on the forgoing definitions and proposals, including any benefits, drawbacks, or unintended consequences. The Department also requests comment on the following considerations in particular:
    a. Whether the definitions the Department proposes to adopt are appropriate. If not, please provide an alternative definition(s) and support for the definition(s).
    b. Whether it is necessary for the Department to define "reproductive health." If so, please provide a definition and support for the definition.
    c. Whether the Department should provide examples of "reproductive health care" in regulatory text, or it is sufficient to provide extensive discussion of the examples in preamble?
    d. Whether it would be helpful for the Department to define any additional terms. If so, please propose a definition and support for the definition and rationale.

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

4. The Department requests comment on the foregoing proposals, including any benefits, drawbacks, or unintended consequences. The Department also requests comment on the following considerations in particular:
    e. Whether the proposed prohibition in section IV.B.2. is sufficiently narrow so as to limit harmful uses or disclosures (such as for investigating individuals who have obtained, or health care providers who have provided, lawful health care primarily because they obtained or provided the lawful health care) and to permit beneficial uses or disclosures (such as for conducting investigations into health care fraud or audits examining general compliance with claims billing requirements). If not, please explain and provide examples.
    f. The effects of individuals' concerns about the potential disclosure of their PHI to law enforcement or others on their willingness to confide in their health care providers.
    g. The effects of individuals' withholding information about their health from their health care providers.
    h. The effects of health care providers' concerns about potential criminal, civil, or administrative investigations into or proceedings against them or their patients in connection with the provision of lawful reproductive health care on the completeness and accuracy of medical records and continuity of care.
    i. Whether it would be beneficial to further clarify or provide additional examples of instances in which the use or disclosure of PHI would be permitted under the proposal, such as examples of type of investigations or

proceedings that are focused on health care fraud and for which PHI is necessary.

j. Whether the Department should permit the use and disclosure of an individual's PHI for the purpose described in section IV.B.2. with a valid authorization from the individual.
    i. If so, please provide recommendations for how the Department could ensure that individuals are adequately protected from coercive tactics to provide such authorization. For example, should the Department permit such use or disclosure based on an authorization only if a regulated entity also obtains some form of attestation or assurance from the recipient of the PHI?
    ii. Whether third parties might 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. If so, please suggest ways the Department could address this problem without curtailing an individual's right of access or increasing the burden on regulated entities.
k. Whether the Department should apply the proposed prohibition broadly to any health care, rather than limiting it to reproductive health care. Please explain.
l. Whether the Department should prohibit or limit uses or disclosures of "highly sensitive PHI" for certain purposes. If so:
    i. How should the Department define "highly sensitive PHI"? Please explain and provide reference materials to support any suggested definition.
    ii. What additional protections should "highly sensitive PHI" be accorded?
    iii. Do regulated entities have the technical ability to differentiate between types of PHI in their electronic record systems and apply special protections to a new category of "highly sensitive PHI"?
    iv. What would be the estimated burden on regulated entities of providing additional protections for "highly sensitive PHI"?
m. Whether in addition to, or instead of, the proposed prohibition, the Department should:
    i. Require a regulated entity to obtain an individual's authorization for certain uses and disclosures of PHI that currently are permitted without an authorization.
    ii. Require a regulated entity to obtain an individual's authorization for any uses and disclosures of a defined category of PHI (e.g., "highly sensitive PHI").
    iii. Require a regulated entity to accept and comply with an individual's request for restrictions of uses and disclosures of "highly sensitive PHI."
    iv. Eliminate or narrow any existing permissions to use or disclose "highly sensitive PHI" (e.g., permissions to report crime on the premises or report crime in emergencies).

n. What are the practices and procedures that a regulated entity currently uses to determine what actions they will take when faced with a conflict of state and Federal laws regarding uses and disclosures of PHI?
o. Whether the scope of the proposed rule of applicability will be sufficiently clear to individuals and covered entities, and whether the provision should be made more specific or otherwise modified to ensure individuals and covered entities know when disclosures of PHI will be permitted.
p. Whether the proposed Rule of Construction is sufficient, or whether the Rule of Construction should be expanded, narrowed, or otherwise modified. Please explain and provide support for this response.
q. Whether the proposed clarification to personal representative status in the context of reproductive health care is sufficient to clarify that personal representatives who provide or facilitate reproductive health care have not committed an act of "child abuse." Please explain and provide support for this response.

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

3. The Department requests comment on the foregoing proposals, including any benefits, drawbacks, or unintended consequences. The Department also requests comment on the following considerations in particular:

r. Whether the proposed attestation requirement in section IV.C. would address all relevant types of permitted uses and disclosures under the Privacy Rule. That is, should the proposed requirement apply as a condition of any additional permitted uses and disclosures that could be used to request uses and disclosures of PHI for a prohibited purpose?
    i. Conversely, would the proposed requirement be overinclusive, placing unreasonable barriers to disclosures for beneficial purposes such that the Department should narrow the scope of the proposed requirement?
    ii. The Department requests comment on specific examples of unreasonable barriers and recommended alternatives.
s. Whether requesters of PHI should be required to name the individuals whose PHI they are requesting, or if describing a class of individuals whose PHI is requested is sufficient. Please explain how the Department can further protect the privacy of individuals from requests for large amounts of PHI ostensibly sought for a non-prohibited purpose if requesters of PHI are permitted to describe a class of individuals whose PHI is requested.
t. How the Department should interpret the terms "practicable" and "class of individuals."
u. Whether a model attestation would be useful for regulated entities.
    i. If so, what other information should be included within such model attestation to improve regulated entities' understanding of the proposed attestation requirements, if adopted?
    ii. What should be the format of a model attestation?
v. Whether the Department should require a particular attestation format, rather than providing a model attestation.

w. How the Department should interpret "combined with" at proposed 45 CFR 164.509(b)(3) with respect to both paper and electronic attestations to minimize the burden on regulated entities of understanding and responding to requests that require an attestation.
x. Whether the Department should consider permitting the attestation to be combined with other types of documents.
    i. If so, which types of documents should regulated entities be permitted to combine with the attestation?
    ii. What potential negative impacts could this have on the clarity of the attestation?
y. Whether the Department should require the attestation to include a signed declaration made under penalty of perjury that the requester is not making the request for a purpose prohibited by this proposal and any ramifications, positive or negative, of such a requirement.
z. Whether there are any other elements that should be included within the proposed attestation that are not currently listed.
aa. Whether the Department should consider it a material misrepresentation if a person who signs an attestation does not have an objectively reasonable basis to suspect that the reproductive health care was provided under circumstances in which it was unlawful. If so, what should the Department consider a reasonable basis for suspicion?
bb. How the proposed attestation requirement would affect a regulated entity's process for responding to regular or routine requests from certain requestors, such as government agencies that request PHI for purposes of health oversight activities. For such requests, what information should such requestors provide to reduce regulated entities' compliance burden associated with the proposed attestation requirements?
cc. Whether there is alternative documentation that a requestor could provide, instead of an attestation, to assist a regulated entity in complying with 45 CFR 164.502(a)(5)(iii). For example, would a notice from a health oversight agency that identifies the objective of an audit, information sought, and the requesting agency provide sufficient information to assure the regulated entity that the audit is not subject to the prohibition at proposed 45 CFR 164.502(a)(5)(iii)? Please provide examples of documentation that may be helpful.

IV.D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity to Agree or Object Is Not Required

4. The Department requests comment on the forgoing proposals, including any benefits, drawbacks, or unintended consequences. The Department also requests comment on the following considerations in particular:
    dd. The way in which regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 CFR 164.512(d) (uses and disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for

law enforcement purposes), or (g)(1) (uses and disclosures about decedents to coroners and medical examiners). Specifically:

i. How are such requests currently submitted (e.g., hard copy letter, electronically via email, an online form)?

ii. For requests under 45 CFR 164.512(e)(1)(ii) and (f)(1)(ii)(C):

i. When using or disclosing information after receiving the required assurances,[1] does the entity choose to obtain assurances for every subsequent related request, or does the entity continue to disclose PHI to such entity after receiving the initial assurance, provided that subsequent requests are related to the initial request in which the initial assurance was received?

ii. How do regulated entities accept assurances (e.g., hard copy letter, electronically via email, uploading to an online portal)?

ee. Examples, if any, of uses or disclosures of PHI that are required by law and are not for prohibited purposes but may no longer be permitted under this proposal.

ff. The effect expanding the scope of the proposed prohibition to include any health care would have on the proposed attestation requirement and the ability of regulated entities to implement it.

gg. Whether the phrase "based primarily" is sufficient to clarify that the proposed rule of construction is only intended to address situations where the purpose is to investigate or impose liability because reproductive health care was provided, rather than, for example, the quality of the health care provided or whether claims submitted for that health care were appropriate.

hh. Whether there are disclosures currently made under Federal agencies' interpretations of the Privacy Act that would not be permitted under the proposal. If so, what would they be, and should the Department permit them?

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

3. The Department requests comment on the foregoing proposals, including any benefits, drawbacks, or unintended consequences. The Department also requests comment on the following considerations in particular:

ii. Whether it would benefit individuals for the Department to require that covered entities include a statement in the NPP explaining that when PHI is disclosed for a permitted purpose to an entity other than a covered entity (e.g., disclosed to a non-covered 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.

V.A. Regulatory Impact Analysis

4. Request for Comment

jj. The Department requests comment on all the estimates, assumptions, and analyses within the cost-benefits analysis, including the costs to regulated entities and individuals.

[1] See 45 CFR 164.512(e)(1)(iii) and (f)(1)(ii)(C).

kk. The Department also requests comments on any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA. Specifically, the Department requests comment on the following:
    i. Whether this proposed rule would affect other activities of regulated entities, including their ability to comply with other laws, and, if so, how.
    ii. Whether the proposed prohibition on the use or disclosure of PHI for a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided would affect the disclosure of PHI between health care providers or between health care providers and health plans for treatment purposes.
    iii. Whether the proposed prohibition on the use or disclosure of PHI for a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided would affect the provision of access to individuals who request copies of their own PHI.
    iv. Data about the costs to regulated entities of determining whether reproductive health care revealed in PHI that is the subject of a request under 45 CFR 164.512(d) through (f) and (g)(1) was lawful under the circumstances in which it was provided.
    v. Data about the costs to regulated entities of determining whether a request for the use or disclosure of PHI is for a prohibited purpose where an attestation is not provided.
    vi. Whether the ongoing cost associated with the burden of responding to requests for PHI with an authorization is an appropriate comparator for the ongoing cost associated with the burden of responding to requests for PHI that may require an attestation.
    vii. The number of requests regulated entities receive annually for uses and disclosures under 45 CFR 164.512(d) through (f) and (g)(1), and the number of individuals' records encompassed by those requests.
    viii. Data about the costs and any other burdens for regulated entities associated with determining that a request is for PHI that is potentially related to reproductive health care.
    ix. Whether the lack of an attestation for some requests received under 45 CFR 164.512(d) through (f) and (g)(1) would increase the time needed to process each request.
ll. The Department also requests comments on whether there may be other indirect costs and benefits resulting from the changes in the proposed rule and welcomes additional information that may help quantify those costs and benefits.

VI. Request for Comment

In addition to the questions posed above, the Department also seeks comment on the following questions:

mm. Whether individuals who are members of historically underserved and minority communities are more likely to be subjects of investigations into or proceedings against persons in connection with obtaining, providing, or facilitating lawful reproductive health care. If so, please explain the relationship to and effects on the health information privacy of community members, including data and citations to relevant literature.

nn. Whether individuals who are members of historically underserved and minority communities are less likely to have access to legal counsel when facing investigations into or proceedings against persons in connection with obtaining, providing, or facilitating lawful reproductive health care. If so, please explain the relationship to and effects on the health information privacy of community members, including data and citations to relevant literature.

oo. With respect to an individual's right to restrict uses and disclosures of their PHI under 45 CFR 164.522(a)(1):

i. Whether individuals are generally aware of this right.

ii. Whether covered entities have experienced an increase in requests from individuals to exercise this right.

iii. Whether regulated entities have been or are more likely to grant individuals such requests considering the recent developments in the legal environment.