Regulatory Brief – Proposed Rule to Support Reproductive Health Privacy (April 2023)

Following the Supreme Court decision in Dobbs, President Biden directed that the Department of Health and Human Services (HHS) and the Federal Trade Commission review existing laws and regulations for opportunities to further bolster reproductive health care. This NPRM is part of that initiative.

FORMAL NAME: HIPAA Privacy Rule to Support Reproductive Health Care Privacy (0945-AA20)

WHAT IS IT: HHS' (partial) response to concerns that protected health information (PHI), specifically reproductive health information (RHI) and lawful services, may be obtained by individuals/organizations for use in the investigation and/or prosecution of a patient or any other person.

AGENCY: Office for Civil Rights (OCR), Office of the Secretary (OS) – HHS

TIMELINE: Published in the Federal Register – April 17th, 2023

60-day comment period closes – June 16th, 2023

WHAT'S IN IT:

Creates/defines a **purpose-based prohibition** on specific uses/disclosures of PHI; provides for additional safeguards (e.g. attestations that disclosed PHI will not be used against patient or another person) when RHI is disclosed. These attestations would be obtained to validate that records were not being obtained for a prohibited purpose or under coercion when a PHI request falls within one of the following categories:

- Judicial/administrative proceedings
- Oversight (health) activities
- Law enforcement activities
- Coroner and medical examiner requests

Introduces a Rule of Applicability for the above purpose-based restriction; the prohibition would be limited to instances where a/the state lacks a substantive interest in RHI. The **Rule of Applicability** holds that the purpose-based prohibition would be effective when reproductive health care is:

1. Provided in a state where it is lawful AND the state authorizing/investigating is different from where reproductive health care was provided

2. Reproductive health care is protected, required, or authorized by federal law; this would apply to all states

3. Reproductive health care provided where such health care is lawful AND that state has authorized or is investigating the reproductive health care.

Discusses a **Rule of Construction** wherein health care providers may still use/disclose PHI to defend a person in administrative, civil, or criminal proceedings but may not disclose PHI for an investigation or administrative, civil, or criminal proceedings against an individual or any other person.

AREAS TO WATCH & CONCERNS

The creation of a purpose-based prohibition will be a foundational shift for Release of Information (ROI) service providers. Recent OCR initiatives have focused on patient access to PHI; the Reproductive Health Privacy NPRM would require ROI staff and organizations to identify requests where a prohibition may apply and to then obtain an attestation from the requester that the requested medical records will not be used against the patient – even when a patient has authorized the release of said PHI.

Under the proposed rule, HHS maintains that the Reproductive Health Privacy NPRM would supersede state laws but that the proposed rule is narrowly tailored to only apply to circumstances where there is not legitimate, substantial interest in obtaining PHI. It is likely that some states will maintain that they have a substantial interest in care being provided outside of its borders.

HHS has asked for feedback on specific questions, including:

- "Should the proposed, required attestation could all such types of permitted uses/disclosures?"

- "Should the proposed requirement (attestation) apply as a condition of any additional permitted uses/disclosures that could be used to request uses/disclosures for prohibited purposes?"

- "Is the requirement (attestations) overbroad and creates barriers to disclosures?"

- Would a "model attestation be useful for regulated entities? … Should there be a mandated format?"
- How the attestation requirement may impact ROI?

NEXT STEPS: Verisma, along with other ROI providers and organizations, will begin work on a comment letter to provide feedback to HHS on the proposed rule and answer the questions set forth in the NPRM. All individuals are welcome to submit comments to HHS via the Federal Register; email compliance@verisma.com if you would like assistance.