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## HEADLINES



## NOTICES


**SUMMER CONFERENCE:** The LHA is hosting its Annual Meeting & Summer Conference on July 22-24 at the Perdido Beach Resort in Orange Beach, AL. Louisiana hospital leaders are invited to join us for an outstanding, high-quality education program with numerous continuing education and networking opportunities. For more information and to register, visit the event webpage. **HOTEL UPDATE:** The Perdido Beach Resort room block is full. To assist with conference accommodations, the LHA has secured an additional room block at the Island House Doubletree Hotel at a rate of $399/night. Reservations can be made by calling 251-981-6100 and referencing the group code CDT910 or by reserving online by or before June 19, 2024.

## ARTICLES

### What Hospitals Really Need to Know About Information Blocking

Written by *Emily Black Grey*, Partner, Breazeale, Sachse & Wilson, L.L.P

The Information Blocking Rules are complex, but many hospitals are just looking for a few, bottom-line answers about effective dates, potential penalties, and whether patients must *really* get access to all lab and imaging results immediately – even if a physician would rather explain potentially devastating results first.

**What is "Information Blocking"?**

"Information Blocking" means a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of Electronic Health Information (EHI) when a healthcare provider knows that the practice is unreasonable and is likely to interfere with access, exchange, or use of the EHI. (Reference 45 C.F.R. §171.103)

**Who Must Comply?**

The rule applies to "Actors" that are not only healthcare providers, but also developers of certified health information technology, health information exchanges, and health information networks who are all prohibited from interfering with access to EHI unless one of the exceptions apply. (Reference 45 C.F.R. §171.101, 102)

**Must Patients Be Given Access to Lab or Radiology Results Before Their Doctor Has a Chance to Review and Explain Them?**

In a word, yes. The Office of the National Coordinator for Health Information Technology (ONC) addressed this issue in its March 2021 FAQs in a response that explained: "It would likely be considered an interference for purposes of information blocking if the healthcare provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or an order to personally inform the patient of the results before a patient can electronically access such results. (*see also* 85 FR 25842 specifying that such a practice does not qualify for the 'Preventing Harm' Exception)."

**What If Releasing the Records Will Cause Significant Distress for the Patient; Isn't There a "Preventing Harm" Exception?**

While there is a "Preventing Harm" Exception, it is limited to physical harm, so it would not generally include emotional or mental anguish. Even though a patient may suffer severe distress upon reviewing bad results before having a discussion with his/her physician, this type of harm does not qualify for the exception. (Reference 45 C.F.R. §171.201)

**Could We Set Up a Policy as a Work Around?**

An organizational policy that provided a blanket restriction would be problematic. The "Preventing Harm" exception is on a case-by-case basis, so a hospital should not set up a policy that, for a certain type of situation, lab results would be withheld, regardless of how emotionally devasting those results might be. The ONC FAQs explain: "*Blanket delays that affect a broad array of routine results do not qualify for the Preventing Harm Exception. The Preventing Harm Exception is designed to cover only those practices that are no broader than necessary to reduce a risk of harm to the patient or another person.*"

**Our Physicians Are Really Concerned About Releasing Test Results Before They Can Talk to Their Patients; Isn't There Anything We Can Do?**

The physicians should address this on a case-by-case basis, and one approach could be:

- The physician could educate the individual patient receiving the test on the Information Blocking rules and explain that the lab/imaging report must be available to the patient immediately on the portal when the hospital receives it, at the same time the physician will receive it.
- The physician can explain that the particular lab or radiology result can be confusing and that if the patient would prefer to meet with the doctor and discuss the results prior to seeing them that it is possible to withhold that and restrict it from the record until the patient has had a chance to talk with the physician about it.
- If the patient agrees, the physician would complete an individualized, patient-specific exception form dated and signed by both the patient and the physician to demonstrate compliance with the exception and avoid allegations of information blocking.

Another instance where the exception form could prove useful is when a patient does not want information appearing on their portal, for example where a patient's spouse has access to their portal, and the patient wants to maintain strict confidentiality of test results (such as for STDs).

**What Happens If a Hospital Violates the Information Blocking Rules?**

ONC and the Center for Medicaid and Medicare Services (CMS) released a proposed rule on Oct. 30, 2023 to establish "appropriate disincentives" for healthcare providers determined by Office of Inspector General (OIG) to have committed information blocking. This proposed rule by ONC and CMS only contained proposed disincentives for healthcare providers that participate in the Medicare Promoting Interoperability or Medicare Shared Savings Program, or that serve a limited number of Medicare beneficiaries. Under the proposed rule, ONC and CMS propose to use the existing Medicare Promoting Interoperability Program for the meaningful use of certified electronic health record (EHR) technology to impose disincentives on eligible hospitals and critical access hospitals (CAH). Under the proposed rule, an eligible hospital or CAH would not be a meaningful EHR user in an EHR reporting period if OIG refers its determination that the eligible hospital or CAH committed information blocking during the calendar year of the reporting period. A hospital would be

unable to earn the three quarters of the annual market basket increase, and the CAH would have its payment reduced to 100% of reasonable cost, down from 101%.

**Is There Any Silver Lining?**
Yes. Providers frequently have difficulty in getting information from Health Information Technology (HIT) vendors, particularly when changing or terminating IT vendors. The Information Blocking rules also apply to health IT developers of certified HIT, health information exchanges, and health information networks. Those entities violate the rule if they know or should know that their practice is likely to interfere with access, exchange, or use of electronic health information. These rules, combined with Federal Trade Commission enforcement against anti-competitive conduct, may even be of assistance to hospitals faced with unreasonable charges from vendors to extract and transfer data. (Reference 45 C.F.R. §171.103)

**Where Do These Rules Come From?**
There are a variety of interrelated rules, including HIPAA, that are implicated, but key statutes and regulations include the 21st Century Cures Act, Section 4004, which amended the Public Health Service Act at 42 U.S.C. §300jj-52, authorizing OIG to investigate claims of information blocking and authorizing the Secretary of the Department of Health and Human Services (HHS) to impose Civil Monetary Penalties (CMPs) for information.

ONC and CMS have also promulgated regulations, including the Information Blocking Rules, at 45 CFR Part 171. Enforcement of the Information Blocking Rule began on Sept. 1, 2023, and enforcers include OIG. There is also a variety of guidance available including the preamble issued with the Final Rule on Information Blocking at 88 Fed. Reg. 42820 (July 3, 2023) and a detailed FAQ page from ONC available online.

*Emily Black Grey is a partner in the Health Care Section of Breazeale, Sachse & Wilson, LLP and practices in the Baton Rouge Office.*

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## Hospitals Face New Duties to Secure PHI for Reproductive Healthcare Under HIPAA Rule

Written by Courtney Hurtig Associate; Matt Harrell, Associate; Beau Haynes, Partner; Phelps Dunbar

HHS revised the HIPAA Privacy Rule on April 26, 2024 to add protections for reproductive healthcare information. The HIPAA Privacy Rule to Support Reproductive Health Care Privacy (the final rule) takes effect on June 25, 2024, and hospitals must comply with most requirements by Dec. 23, 2024.

The final rule arises out of the 2022 Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*. In response to the decision, state and local governments have taken varying approaches to investigate and regulate reproductive healthcare. The department's stated purpose for the final rule is to ensure that individuals are not afraid to seek healthcare from, or share important information with, their healthcare providers because of a concern that their sensitive information will be disclosed outside of their relationship with their healthcare provider. HHS is particularly concerned with disclosure of a patient's protected health information (PHI) about reproductive healthcare for certain non-healthcare purposes, where such use or disclosure could be detrimental to the patient or another individual's privacy.

The final rule seeks to prohibit hospitals and other regulated entities from using or disclosing PHI to identify an individual, healthcare provider, or other person for the purpose of initiating an investigation or proceeding in connection with seeking, obtaining, providing, or facilitating reproductive healthcare that is lawful under the circumstances in which it is provided.

To that end, the final rule adopts a new definition of "reproductive healthcare" and imposes a requirement that, in certain circumstances, hospitals must first obtain an attestation that a requested use or disclosure is not for a prohibited purpose.

The final rule also changes the required contents of the Notice of Privacy Practices (NPP) that all hospitals must make available to patients and their representatives. These include language relating to new protections for reproductive healthcare and recent changes to privacy laws governing substance use disorder treatment records.

Hospitals should carefully review the final rule and make sure they update their HIPAA policies and procedures and their NPPs to comply with these changes. Keep reading for an outline of the major new requirements.

**Definition of "Reproductive Healthcare"**
The final rule adopts the new term—"reproductive healthcare"—to mean healthcare "that affects the health of the individual in all matters relating to the reproductive system and its functions and processes." This definition is intentionally broad in scope.

As part of the final rule, HHS published a non-exclusive list of examples that fit within the definition:

- Contraception, including emergency contraception;
- Diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis);
- Fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization);
- Management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment of preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination;
- Other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products); and
- Preconception screening and counseling.

HHS clarified that information meeting this definition must also meet the definition of PHI to be protected under HIPAA rules.

**Attestation for Use or Disclosure of PHI "Potentially Related to Reproductive Healthcare"**

**1. Attestation**
The Privacy Rule currently separates uses and disclosures of PHI into three categories: required, permitted, and prohibited. Under the final rule, HHS is now requiring hospitals to obtain an attestation from persons requesting the use or disclosure of PHI "potentially related to reproductive healthcare," stating that the use or disclosure is not for a prohibited purpose.

The attestation must meet specific requirements including:

- Be written in plain language;
- Include the person requesting the disclosure and confirm the types of PHI that they are requesting;
- Clearly identify the name of the individual (or class of individuals) whose PHI is being requested;
- Confirm in writing that the use or disclosure is not for a prohibited purpose; and
- Include a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses individually identifiable health information relating to another individual, or discloses such information to another person, may be subject to criminal liability.

The attestation may be presented in electronic format and be electronically signed by the person requesting the disclosure where such electronic signature is valid under applicable law. However, there are format requirements. The attestation cannot contain any elements that are not specifically required and cannot be combined with other documents. It must be clearly labeled, distinct from any surrounding text, and completed in its entirety. A person requesting PHI is not required to use the specific attestation form provided by the regulated entity, as long as the attestation provided by the requestor is compliant with the regulations.

The regulated entity may use the information on the attestation, combined with any additional documentation provided by the person making the request for PHI, to make a reasonable determination that the attestation is true.

Additionally, both hospitals and their business associates are directly liable for compliance with the attestation requirement, regardless of whether compliance with the new regulations is explicitly mentioned in a business associate agreement.

**2. Evaluation of Attestation and Disclosure**

HHS is not requiring hospitals to investigate the validity of an attestation provided by a person requesting a use or disclosure of PHI. Rather, hospitals are generally permitted to rely on the attestation if under the circumstances, they reasonably determine that the request is not for investigating or imposing liability for seeking, obtaining, providing, or facilitating allegedly unlawful reproductive healthcare or that the use or disclosure is not for a prohibited purpose.

However, for requests involving allegedly unlawful reproductive healthcare, the extent to which a hospital may reasonably rely on an attestation depends in part on whether it provided the reproductive healthcare at issue. To determine whether it is reasonable to rely on the attestation of a law enforcement official requesting PHI potentially related to reproductive healthcare, HHS directs hospitals to consider, among other things:

- Who is requesting the use or disclosure of PHI;
- The permission the person is relying on to make the request;
- The information provided to satisfy the other conditions of the relevant permission;
- The PHI requested and its relationship to the stated purpose of the request; and
- If the reproductive healthcare was supplied by another person, whether the hospital has:
    - Actual knowledge that the reproductive healthcare was not lawful under the circumstances in which it was provided; or
    - Factual information from the petitioner that gives a substantial factual basis that the reproductive healthcare was not lawful under the circumstances in which it was provided.

Lastly, the final rule requires a hospital to cease use or disclosure of PHI if it discovers that the representations in the attestation are materially incorrect, leading to uses or disclosures for a prohibited purpose.

**3. Repercussions and Penalties**

HHS highlighted that people will be subject to criminal liability if they knowingly and in violation of HIPAA obtain or disclose individually identifiable health information relating to another individual or disclose such information to another person. Thus, a person who knowingly and in violation of HIPAA falsifies an attestation, such as making material misrepresentations about the intended use of PHI requested, to obtain (or caused to be disclosed) an individual's PHI could be subject to criminal penalties as outlined in the statue. Additionally, once a hospital becomes aware of such misrepresentations, a disclosure made based on that attestation constitutes an impermissible disclosure. This requires the hospital to notify the individual, the HHS Secretary, and in some cases, the media, of the breach.

**Changes to Notice of Privacy Practices**

The final rule also modifies the required contents for the NPPs outlining hospitals' legal duties with respect to PHI. Hospitals will need to update their NPPs by Feb. 16, 2026, to include:

1. A description of prohibition on the use or disclosure of PHI for an investigation of a person seeking, obtaining, providing, or facilitating reproductive healthcare;
2. A description of the types of uses and disclosures of PHI for which an attestation is required under 45 C.F.R. § 164.509 (as described above); and
3. A statement that PHI disclosed under the HIPAA Privacy Rule is subject to redisclosure by the recipient and is no longer protected by the Privacy Rule.

Additionally, hospitals that create or maintain substance use disorder treatment records subject to 42 C.F.R. Part 2 must also revise their NPPs to include:

1. A description of the permitted uses and disclosures of PHI under HIPAA, reflecting more stringent requirements under Part 2 or other applicable law;
2. A separate statement that substance use disorder treatment records shall not be used in civil, criminal, administrative, or legislative proceedings without written consent or a court order; and
3. A separate statement that, if the covered entity intends to use Part 2 records for fundraising, the patient or individual must be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

The Privacy Rule's requirements for the NPPs have not been updated since the 2013 Omnibus Rule following enactment of the HITECH Act. Hospitals should take this opportunity to revisit their NPPs to ensure they meet current regulatory requirements.

Courtney Hurtig, Matt Harrell, and Beau Haynes are lawyers at Phelps, with offices in Baton Rouge, New Orleans, and across the Gulf South. They can be reached at courtney.hurtig@phelps.com, matthew.harrell@phelps.com, or beau.haynes@phelps.com.


For a complete listing of education opportunities, visit the LHA's Upcoming Events webpage.

- **Common Hospital Compliance Standard Deficiencies;** June 4; Webinar; Register
- **Behavioral Health Law Update;** June 18; Seminar; 2.75 Nursing CEUs Available; MCLEs and HLS Applied for; Register
- **LHA Annual Meeting & Summer Conference;** July 22-24; Orange Beach, AL; Register