

Compliance Resource - Defining Reproductive Health Data

HHS OCR HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Background

The Biden-Harris Administration, through the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR), released the <u>HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule</u> on April 22, 2024. The final rule modifies the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information (PHI) related to reproductive healthcare. The final rule made several adjustments to the proposed requirements in response to public comments, including <u>comments provided by AHIMA</u>. The final rule became effective on June 25, 2024, and **the compliance date is December 22, 2024**. Updates to the provider's Notice of Privacy Practices (NPP) are due February 16, 2026, giving providers additional time to comply.

Modifications to the HIPAA Privacy Rule include a prohibition on regulated entities using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the act of seeking, obtaining, providing, or facilitating reproductive healthcare that is lawful under the circumstances in which it is provided. The rule requires regulated healthcare providers, health plans, clearinghouses, and business associates (BAs) to obtain signed attestations from individuals requesting PHI potentially related to reproductive healthcare. The attestation must state that the information will not be used against a provider or patient in legal cases related to the provision of reproductive healthcare.

To comply with these new requirements by December 22, 2024, healthcare organizations should begin to develop policies and procedures pertaining to "reproductive healthcare" that could be used to make initial determinations of whether PHI is potentially related to reproductive healthcare and whether an attestation is required. Healthcare organizations should document these policies and create decision matrices that assess whether PHI is potentially related to reproductive healthcare, whether an attestation is required, and incorporates release of information processes. This resource is intended to assist with the first step of this work, assessing what data constitutes "reproductive healthcare."

Defining "Reproductive Healthcare" Data

HHS OCR defines "reproductive healthcare" as, "healthcare that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes. The definition should not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive healthcare."

Non-exclusive list of examples of reproductive healthcare provided by OCR in the final rule include: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and

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¹45 CFR 160.103.



pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis); and 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).

Importantly, OCR notes that either a provider or patient/individual may determine whether received healthcare, such as over-the-counter contraceptives, is reproductive healthcare.

Organizations should review their policies and utilize the OCR definition of "reproductive healthcare" to prepare their own definitions of data potentially related to reproductive healthcare. Data may include elements from the non-exclusive list of services described by OCR as well as additional elements derived from healthcare not explicitly included in the list provided by OCR. Organizations should document in their organizational policy for reference their determination of which data elements are included in their definition of data potentially related to reproductive healthcare.

Value Set Authority Center

The Value Set Authority Center (VSAC), provided by the National Library of Medicine (NLM) and in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS), is an authoring tool and repository for public value sets created by external organizations and programs. The VSAC is a place where collections of codes from various code sets (including CPT, ICD-10, HCPCS, LOINC, RxNorm, and SNOMED-CT), organized under a specific topic, are collated and posted publicly for organizations to use as resources.

The National Association of Community Health Centers (NACHC) created and maintains value sets in VSAC that may be included in a healthcare organization's definition of data potentially related to reproductive healthcare. The value sets include but are not limited to abortion and related services, contraception, infertility, miscarriage management, and prenatal care. There are also value sets created by NACHC in the VSAC that are not related to reproductive healthcare.

The value sets in VSAC are a comprehensive resource to assist organizations in creating their definitions of data potentially related to reproductive healthcare. The collections of codes from several code sets reflect many of the elements of reproductive healthcare included in the non-exclusive list provided by OCR, which can serve as a starting point for organizations to begin creating their organizational policies for compliance with the final rule.

Using VSAC Value Sets to Support Compliance

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To take advantage of the VSAC value sets, organizations may download the VSAC value sets for incorporation into an organization's electronic health record (EHR) and create, document, and implement policies and procedures for evaluating requests for PHI potentially related to reproductive healthcare and potentially disclosing information to a requestor.

Just as an organization determines their designated record set (DRS), organizations must also determine what data they consider to be potentially related to reproductive healthcare. Additionally, the organization must work with patients to determine whether the organization's definition excludes data that a patient considers potentially related to reproductive healthcare. The value sets in the VSAC data sets may be used by an organization as a starting point to develop their own data set. However, it is important to note that the VSAC data set does not contain all information that may be potentially related to reproductive healthcare.

Provider organizations should work with their health information experts, clinicians, compliance professionals, and legal staff to determine and finalize their data set potentially related to reproductive healthcare. Organizations should ensure the most recent version of their data set is codified in the policies and procedures regarding the release of information process and attestation. New technologies, treatments, and methodologies will need to be added to the data set as reproductive healthcare evolves. Organizations should consider establishing a routine process to review and update data sets as needed. Establishing such practices in policies and procedures will help ensure a more consistent application of requirements across all data requests.

How to Access, Navigate, and Use VSAC

Individuals can <u>request a free UMLS License</u> to access the VSAC value sets. Please note it may take one to five business days to obtain a license. In creating a license, consider who the owner of the account should be, as the individual's login will be the only way to access the value sets. Logins are created for individuals, not organizations. Organizations can take the following steps to find the NACHC authored value sets in VSAC related to reproductive health and export them for use:

- Visit <u>vsac.nlm.nih.gov</u> and login with your UMLS account.
- Click "Search" in the "All Value Sets" box in the lower left area.
- Navigate to the "Refine by" section at the top and under the drop-down box for "Steward" select "NACHC" and click the orange "Search" button.
- Under "Search Results" below the search boxes, you will find value sets comprised of various codes, organized by topic.
- To view a value set, click on the OID number which will take you to a webpage with that value set. Scroll down and navigate through the pages to view the codes included in a value set.
- To download the value set, under "Value Set Details" click the "Export Value Set Results" with the green Excel icon. This will download an excel sheet with the full value set and codes for your use.
 - You can export multiple value sets at once by clicking the white box on the left of each value set row and clicking "Export Value Set Results."

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If you have questions about the provisions and requirements in the HHS OCR HIPAA Privacy Rule to Support Reproductive Health Care Privacy final rule, please contact the AHIMA Policy & Government Affairs team at advocacy@ahima.org.