

Report on Research Compliance Volume 21, Number 5. April 25, 2024 RRC E-Alerts: April 4, 2024

By Theresa Defino

HHS Issues Warning to Medical Schools, Teaching Hospitals About Informed Consent for 'Sensitive' Procedures

Federal health officials are aware that, "as part of medical students' courses of study and training, patients have been subjected to sensitive and intimate examinations – including pelvic, breast, prostate, or rectal examinations – while under anesthesia without proper informed consent being obtained prior to the examination," HHS said in an April 1 letter to medical schools and teaching hospitals. HHS said it is "critically important" to "set clear guidelines to ensure providers and trainees performing these examinations first obtain and document informed consent from patients before performing sensitive examinations in all circumstances." HHS also noted that "informed consent includes the right to refuse consent for sensitive examinations conducted for teaching purposes and the right to refuse to consent to any previously unagreed examinations to treatment while under anesthesia." HHS's Centers for Medicare & Medicaid Services (CMS) also issued a revised "interpretive guidance" document to its state surveyors to ensure they are documenting hospitals have such processes and are complying with them.

The HHS Office for Civil Rights (OCR) issued a companion FAQ document, which notes that patients can request restrictions on the disclosure of their protected health information (PHI), particularly related to such examinations. However, covered entities are not required to agree to the request. But if they do, "the provider may not use or disclose the individual's PHI to medical trainees, even if the medical trainees are members of the covered health care provider's workforce, **with the result that the medical trainees cannot be in the room with the individual and their PHI, or otherwise have access to the individual's PHI.** As such, the restriction would prevent the medical trainees from observing or providing treatment to the individual, except as needed to provide emergency treatment or where another exception applies," OCR said. In the letter to hospitals, HHS added that OCR "investigates complaints alleging that patients' protected health information was used or disclosed to medical trainees in violation" of HIPAA. "OCR also enforces federal civil rights laws, such as Section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of sex, race, national [origin], age, and disability. OCR has previously worked with, and will continue to work with, covered entities to ensure that their policies and practices related to sensitive examinations do not discriminate against patients on any of these bases," HHS said.

[Link to HHS letter](#)

[Link to CMS guidance](#)

[Link to OCR FAQ](#)

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)