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Updated Requirements for Informed Consent: HHS Issues New Guidance on Sensitive Exams

Article By:

Arthur J. Fried

Jennifer (Jenny) M. Nelson Carney

Kyla Portnoy

On April 1, 2024, the U.S. Department of Health and Human Services ("HHS") released new guidance which requires hospitals to obtain informed consent from patients before practitioners, or medical or other students, perform important surgical tasks or sensitive or invasive procedures or examinations ("Guidance"). The Guidance aims to address increasing concerns over patient privacy, in particular the performance of sensitive examinations and invasive procedures on anesthetized patients.

The Guidance both revises the Hospital Interpretive Guidelines regarding informed consent and clarifies the Centers for Medicare and Medicaid Services ("CMS") expectations for hospitals.[1] The changes described in the Guidance are effective immediately.

Summary of the Guidance

According to the Guidance, hospitals must ensure that their patient informed consent policy and process, as well as informed consent forms, contain elements and information that allow for a patient, or his or her representative, to make fully informed decisions about the patient's care. In the Guidance, CMS emphasizes the importance of patients making informed decisions about their healthcare to include any training and education-related examinations or procedures that may be performed in addition to the care the patient expected to receive. CMS emphasizes the particular importance of a patient's informed consent to services to be provided while the patient is under anesthesia, inclusive of being made aware of who will be conducting the examination or procedure and its nature and purpose.

To provide clarity around this issue, CMS revised its examples of a properly executed and well-designed informed consent form in the Hospital Interpretive Guidelines as follows (new guidance in italics and bold):

Whether physicians other than the operating practitioner, including, but not limited to,

residents, ***medical, advanced practice provider (such as nurse practitioners and physician assistants), and other applicable students***, will be performing important tasks related to the surgery, ***or examinations or invasive procedures for educational and training purposes***, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices, and placing invasive lines. ***Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.***

The Guidance and associated letter to the nation's teaching hospitals and medical schools from HHS Secretary Xavier Becerra (the "Letter") indicate that hospitals should set clear guidelines to ensure providers and trainees performing sensitive examinations and invasive procedures first obtain and document informed consent from patients. The Letter makes clear that informed consent "includes the right to refuse consent for sensitive examinations conducted for teaching purpose and the right to refuse to consent to any previously unagreed examinations to treatment while under anesthesia."

Implications for Hospitals

Hospitals should be prepared for increased scrutiny of their informed consent processes and documentation during the survey process and should review policies, processes, and forms to ensure compliance with the new Guidance. Likewise, medical staff policies should be reviewed to ensure such policies address which procedures and treatments require written informed consent. Hospitals should also ensure that applicable state laws are incorporated into their consent process and documentation.

The new Guidance provides an opportunity for hospitals to update their provider and staff training and education around the consent process. Hospitals should emphasize the importance of providing patients with adequate information in a manner that patients can understand to ensure that patients can effectively exercise their rights to make informed decisions and protect their bodily autonomy.

ENDNOTE

[1] The requirements related to informed consent for hospitals are found in the Patient's Rights Condition of Participation (CoP) at 42 CFR § 482.13(b)(2); the Medical Record Services CoP at § 482.24(c)(4)(v); and the Surgical Services CoP at § 482.51(b)(2), and are further described in the State Operations Manual (SOM), Appendix A.

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