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CMS Revises Informed Consent Requirements for Sensitive Procedures; OCR Updates Related FAQ

By Nina Youngstrom

To stay in good standing with Medicare, hospitals are now required to ask patients for permission before medical and other students perform pelvic, prostate and other sensitive exams and procedures on them during surgery. In an April 1 memo to state surveyors, CMS said it revised the interpretive guidelines on informed consent to make it clear that hospitals must be sure patients understand what will happen when they're under the knife—with sedation—and can say no if they don't like the idea.^[1]

From now on, when surveyors evaluate compliance with Medicare's conditions of participation (CoP), they will be checking whether the informed consent process—in writing and in practice—ensures patients agree to let medical, advance practice provider (APP) and other students do exams or invasive procedures for educational and training purposes (residents were already mentioned in the interpretive guidelines). "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," according to the memo, which was written by CMS's directors of the Quality, Safety & Oversight Group and Survey & Operations Group.

Hospitals may not be paying attention to this as much as they should, said attorney Rachel Carey, with Whiteford in Richmond, Virginia. "I don't know if they will pay attention to it until they are tagged in a survey." A tag refers to a CoP deficiency.

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