

FAQ: CMS Updates to State Operations Manual Patient Informed Consent Requirements for Sensitive Examinations

Updated: April 2024

Background:

The US Centers for Medicare & Medicaid Services (CMS), in conjunction with the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR), [released new guidance](#) via a revision in the State Operations Manual, Appendix A-Hospitals, related to informed consent for training and education-related examinations outside the medically necessary procedure.

CMS states the guidance and revision was published “based on increasing concerns about the absence of informed patient consent prior to allowing practitioners or supervised medical, advanced practice provider, or other applicable students to perform training and education-related examinations outside the medically necessary procedure (such as breast, pelvic, prostate, and rectal examinations), particularly on anesthetized patients.”

Key Revisions to the State Operations Manual:

- Informed consent must be given by the patient for medical, advanced practice provider (such as nurse practitioners and physician assistants), and other applicable students, in addition to the operating practitioner and residents, for examinations or invasive procedures for educational and training purposes in addition to important surgical tasks; and
- Examinations or invasive procedures conducted for educational and training purposes are defined to include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.

Key Provisions:

- The updated guidance is effective the date of publication, **April 1, 2024**;
- Impacted providers are those subject to the CMS Hospital Conditions of Participation;
- Organizations found out of alignment will be found to have violated their Conditions of Participation; and
- Organizations who wish to contact CMS for additional information on this update to the State Operations Manual should contact QSOG_Hospital@cms.hhs.gov.

If you have questions about this update to the State Operations Manual or the Hospital Conditions of participation, please contact us at advocacy@ahima.org.