DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-24-10-Hospitals

DATE: **April 1, 2024**

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions and clarifications to Hospital Interpretive Guidelines for Informed Consent

Memorandum Summary

- 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, we are reinforcing hospitals' informed consent obligations.
- **Requirements related to informed consent for hospitals are found throughout the Hospital Conditions of Participation (CoPs)**: the Patient's Rights 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).
- **Surveyors must ensure** that a hospital's patient informed consent policy and process, as well as its informed consent forms, contain elements and information that allow for a patient, or his or her representative, **to make fully informed decisions about their care.**
- **CMS is revising its hospital interpretive guidance about informed consent** in the State Operations Manual, Appendix A-Hospitals, to address this.

Background

According to a recent article on the *Annals of Surgery Open* website, "A growing number of states have statutes regulating the performance of sensitive examinations on anesthetized patients. The scope of the examinations covered includes breast, pelvic, prostate, and rectal examinations, increasing the impact of these laws on surgeons. There is a broadening focus on obtaining consent for any provider and learner performing these examinations."[1] This focus on the role of patient informed consent to obtain patient permission to perform these examinations

[1] *Annals of Surgery Open* 3(1):p e120, March 2022. | *DOI:* 10.1097/AS9.0000000000000120

has prompted CMS to reinforce the Hospital CoPs to revise our interpretive guidance regarding informed consent, and to clarify our expectations for hospitals regarding this issue.

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.

Informed Decisions

The right to make informed decisions regarding care presumes that the patient or the patient's representative has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's or the patient's representative's participation in the development of his/her plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to ensure that the patient or the patient's representative can effectively exercise the right to make informed decisions. Hospitals must establish processes to ensure that each patient or the patient's representative is given information on the patient's health status, diagnosis, and prognosis. Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that ensures patients, or their representatives, are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See Appendix A, SOM at tag A-0131 for more information.

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed. See Appendix A, SOM at tag A-0466 for more information.

Informed Consent Forms

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place.
- Name of the specific procedure, or other type of medical treatment for which consent is being given.
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment.
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal

representative. (Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.)
- Signature of the patient or the patient's legal representative.
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:
- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative.
- Statement, if applicable, that physicians other than the operating practitioner, including, but not limited to, residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

(See also Appendix A, SOM at tag A-0466.)

Discussion

Recent articles in both the mainstream media[2] as well as medical and scientific literature[3,4] have brought public attention to the traditional practice of allowing practitioners or supervised medical, advanced practice provider, or other applicable students to perform pelvic and other invasive examinations on patients who are under anesthesia. With this attention, patient advocates, physicians, and the students themselves have expressed concern about whether patients, especially anesthetized patients, have been sufficiently informed about this practice and whether their full consent was obtained before these educational exams were performed.[5,6]

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[2] Goldberg E. She didn't want a pelvic exam. She received one anyway. *The New York Times*. Feb. 17, 2020.
[3] *Annals of Surgery Open* 3(1):p e120, March 2022. | *DOI:* 10.1097/AS9.0000000000000120
[4] Obstet Gynecol. 2019 Dec; 134(6): 1303–1307.
Published online 2019 Nov 6. doi: 10.1097/AOG.0000000000003560
[5] Accessed at: https://www.reliasmedia.com/articles/be-careful-about-informed-consent-if-pelvic-exams-happen-while-patients-are-under-anesthesia.
[6] Accessed at: https://ny1.com/nyc/all-boroughs/news/2023/05/20/more-states-requiring-patients-to-give-consent-for-medical-students-performing-pelvic-exams

While CMS recognizes that these patient exams are often conducted as part of the vital skills clinical students must obtain during their training and education, we also firmly believe that patients have the right to make informed decisions on the healthcare services they receive so that they can give their full consent for those services including any training- and education-related examinations that may be performed in addition to any treatments or procedure that they expect to receive, especially if those patients will be under anesthesia at the time.

Therefore, we are revising our interpretive guidance in the State Operations Manual (SOM), Appendix A for hospitals at tag A-0955, to include under the example of a properly executed and well-designed informed consent form, as well as the hospital's policy and process for informed consent, the following elements (in addition to those outlined above) [new guidance in italics]:

- Whether *practitioners* other than the operating practitioner, including, but not limited to, *other physicians,* residents, *advanced practice providers, and medical and other applicable students (such as nurse practitioner and physician assistant)*, 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.*

- *A written consent form is required for patients undergoing anesthesia procedures, but patients with the ability to verbally affirm consent for procedures that do not require anesthesia should have their medical record reflect that consent was given. In both instances there is written documentation of consent for any examinations.*

While CMS understands that the performance of such examinations has been necessary for teaching medical and other students critical clinical examination skills, we believe that patient permission for these exams is an essential part of the informed consent process for hospitals, and necessary for compliance with the informed consent requirements in the CMS hospital CoPs.

Contact: For questions or concerns, please contact QSOG_Hospital@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/

Karen L. Tritz
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David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.