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Revisions to CMS Interpretive Guidelines for Informed Consent

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It is well understood that Informed Consent is a process whereby the patient receives information regarding their diagnosis, prognosis, and options, including the potential risks and benefits of any planned treatments or procedures. Thorough information allows the patient and/or their representative to participate in the planning of care and treatment, and to make educated decisions.

Hospital policies are required to identify which types of procedures require documentation of Informed Consent, as not all procedures require this process and may be covered by the general consent for treatment ("Conditions of Admission"). For example, starting a peripheral intravenous (IV) access, administering medications, and obtaining vital signs are all usually covered with a general treatment consent which is usually obtained upon admission. But more invasive treatments or procedures often require that an Informed Consent be obtained. For example, a central line insertion, dialysis treatments, and surgical procedures (whether performed under local or general anesthesia). Hospital policies should be reviewed to confirm that it is clear when Informed Consent is to be obtained.

Best practice would be that the practitioner who will be performing the treatment/procedure would be the one to have the informed consent discussion with the patient or their representative. However, when this is not possible it would be prudent to have another practitioner who has the clinical privileges to perform the proposed treatment or procedure to conduct the discussion. This is because someone with the education, experience, and knowledge of the proposed treatment or procedure would best be suited to answer any questions that the patient and their representative may ask.

Hospital policies may also prescribe where the Informed Consent may be documented. For example, some organizations may have a dedicated form, whereas most allow this to be recorded within the History and Physical, a Progress Note, or a Consult Note. If not documented in physician documentation, a properly executed Informed Consent form should minimally include documentation of the name of the hospital where the procedure is to occur, the name of the procedure/treatment to be performed, the name of the proceduralist who will perform the procedure/treatment, a statement that the risks, benefits, and alternatives were discussed with the patient or their representative, and the patient's/representative's signature (including the date and time of the signature). This should all be confirmed to be documented in the patient's medical record PRIOR TO the performance of the proposed treatment or procedure.

It is noteworthy that the Informed Consent process should include discussion around ALL potential procedures and treatments that could be performed. On April 1, 2024, the Centers for Medicare and Medicaid Services (CMS) issued QSO-24-10-Hospitals at https://www.cms.gov/files/document/qso-24-10-hospitals.pdf which describes revisions and clarifications to the Hospital Interpretive Guidelines for Informed Consent. The clarifications were prompted by recent articles regarding sensitive, invasive examinations that were traditionally being conducted for the purposes of learning, especially with anesthetized patients, that include the breast, pelvic, prostate and anal regions. These examinations are frequently conducted for the purposes of education and may not be associated with the patient's primary procedure. Thus, concerns

were raised that the patient and/or their representative had not been informed, and therefore not requested to consent for anything beyond the planned procedure.

The Interpretive Guidelines have been revised to include other practitioners and students who may participate in the procedure in addition to the primary proceduralist, as well as the addition of verbiage around “examinations or invasive procedures for educational and training purposes” including but not limited to the breast, pelvic, prostate, and rectal areas. While it is recognized that these training opportunities are beneficial to current and future healthcare providers, the position of the CMS is that the patient has the right to know and should have the opportunity to consent or refuse to allow, these examinations.

Also, any procedures to be performed under general anesthesia do require a documented Informed Consent For those surgeries not performed under general anesthesia or moderate sedation, the hospital policies should guide whether or not the consent can be written or verbal. In either case, it is required that there is written documentation of the consent.

Hospitals are advised to make revisions to their Informed Consent policy and related forms if applicable, and to educate the providers regarding the new requirements from CMS related to any invasive examinations for training purposes.