U.S. Department of Health Clarifies Informed Consent Guidance for Sensitive Medical Examinations



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On April 1, 2024, the United States Department of Health and Human Services (HHS) issued new guidance clarifying the obligation of hospitals to obtain a patient's written consent prior to performing certain sensitive exams, such as pelvic, breast or prostate exams, particularly with respect to patients who are under anesthesia during the exam. The new guidance was issued as a result of public scrutiny regarding the practice of allowing practitioners or supervised medical, advanced practice providers or other healthcare students to perform sensitive examinations that are not related to the condition for which the patient is seeking treatment, such as breast, pelvic, prostate, and rectal examinations, for training and education purposes, including on patients who are under anesthesia. In its new guidance, HHS emphasizes that a hospital's informed consent policy and process, and all informed consent forms, must ensure that patients are provided with sufficient information to allow them to make informed decisions regarding the full scale of care they are to receive. Hospitals that fail to adhere to the updated informed consent guidelines may be subject to investigations, fines and sanctions.

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For more information, contact:

Edward J. Yun | 973.364.5229 | eyun@bracheichler.com **Paul DeMartino** | 973.364.5228 | pdemartino@bracheichler.com