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Informed Consent Process in Ambulatory Surgery

Review state laws and AHRQ materials before creating your policy

BY NESKO RADOVIC AND SANDRA JONES, CASC

Editor's note: This is part two of a two-part column. Look for the first part on page 28 of the October 2019 issue of ASC Focus.



In rare situations, the duration of the informed consent could present

an issue. Some state laws presume that a written authorization signed by the patient is valid. Some states might specify the time frame in which consent remains valid; others require that consent be obtained no more than 30 days from the procedure. Therefore, checking state regulations is essential. For example, Florida's consent statute does not contain any date restrictions, while Georgia law, with some nuances, states that a consent is valid for 30 days. Overall, however, the informed consent process includes discussion of the risk and rewards based upon the history and physical condition of the patient at the time the procedure will be performed. The validity of a consent form executed a week prior to the procedure could be challenged if the patient's condition at the time of the procedure changed the risks involved with the procedure.

In Florida, for example, two physicians must evaluate the patient, determine that a patient lacks capacity to make healthcare decisions, document this in the medical record and notify the healthcare surrogate or the attorney that the patient became incapacitated, thus placing the decision making on the surrogate. Once the patient regains capacity, the patient possesses full authority to make his or her own decisions.

Before delegating the decision-making to a surrogate, ASC staff should refer



to the patient's advance directive, if one is on file. Advance directives encompass any written instruction, such as a living will, durable power of attorney for healthcare, recognized under state law, relating to the provision of healthcare when the individual is incapacitated. Do-Not-Resuscitate orders (DNR) also fall into this category. The advance directive may limit decision making to end-of-life circumstances rather than the normal course of healthcare services.

In the absence of an advance directive that covers authority for normal course of healthcare decisions, state regulations specify who can serve as a proxy to make healthcare decisions when the patient is incapacitated. The regulations specify the individuals as well as the order of priority in decision-making. Consistent with the informed consent process, the proxy must receive relevant information to have a general understanding of the procedure, substantial risks and medically acceptable alternatives. In Florida, for example, the priority order is:

1. court appointed guardian;
2. patient's spouse;
3. an adult child of the patient or the majority of adult children of the patient if the patient has more than one adult child;
4. a parent of the patient;
5. the adult sibling of the patient or a majority of the adult siblings if the patient has more than one;

6. an adult relative of the patient who has exhibited special care and concern for the patient by having regular contact and familiarity with patient's beliefs;
7. a close friend of the patient;
8. a clinical social worker.

A facility's policy should be clear on who can make care decisions for incapacitated patients, the order in which the authority shifts to proxies and how to document the authority in patient's medical record. Staff should be educated and trained on policies and procedures in these situations. Most, if not all, states will have priority rankings of persons who can serve as a proxy. Tennessee law contains information about healthcare decision-making in several statutes including section 1200-08-10-.13 in its Standards for Ambulatory Surgical Treatment Centers. South Carolina also requires that two physicians document incapacity and provides the order of consent priority for a patient determined to be incapacitated. Knowing a state's regulations on the consent priority and recording requirements, as well as procedures for contacting the person who can make decisions, is essential. Just because a friend drove the patient to the surgery center for the procedure and is acting as the responsible adult companion to which the patient will be discharged does not give the patient's friend priority over the patient's spouse, children, parents, adult siblings or adult relatives. Florida statutes even provide a definition of "a close friend." It is essential that ASC leadership and staff know their state regulations about who can make decisions, when and how advance directives can be implemented, who has the authority to consent or refuse the treatment when there are no advance directives and if there is a difference in con-

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sent requirement when the patient is in a medical emergency or end of life care.

The inconvenience of procedure cancellation is only one reason to know state laws and review processes, but another more important reason for being prepared is knowing what to do when the patient has received pre-operative medication that can affect mental capabilities or is under anesthesia when the physician discovers that another procedure was necessary or beneficial and that procedure is not covered by the patient's consent, or not clearly covered in the informed consent process. Assuming the additional procedure is not an emergency, in which case the physician could proceed under the exceptions to the informed consent process, should the physician seek another person to give consent? Or, should the additional procedure be performed at a later date? If the spouse is not present or cannot be reached but would be able to participate

in an informed consent process for the additional surgery if he or she could be reached, should the physician go down the list of priorities until he finds someone available who can be reached and give consent? If the additional procedure is not a medical emergency, completing the current procedure and discussing the possibility of additional surgery at a later date with the patient might be a safer course. In most cases, two physicians must document the incapacity of the patient before healthcare decisions may be made for the patient by anyone else.

To help prevent last-minute cancellations of surgery and decrease the risk of lawsuits based on the consent process, make a list of circumstances that have presented or may present concern among the physicians and staff about the informed consent process. Review the organization's policy. Consider reviewing the material on the Agency for Healthcare Research and Quality website titled

“AHRQ’s Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals.” There are two modules, each 90 minutes long, available at ahrq.gov/professionals/systems/hospital/informedchoice/index.html that can provide additional thoughts about physician and ASC staff roles in the informed consent process. Review material available from the facility’s and physicians’ medical malpractice insurers on the insurers’ website or through conferences. Finally, have a meeting with medical staff leadership and an attorney knowledgeable in healthcare law to review the facility’s processes and make suggestions to improve. ◀◀

Nesko Radovic is an associate with McGuireWoods LLP in Chicago, Illinois, and Sandra Jones, CASC, is the president and chief executive officer of Ambulatory Strategies Inc. in Dade City, Florida. Write Radovic at nradovic@mcguirewoods.com and Jones at sjones@aboutasc.com.

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