COSMOS
Navigate the Compliance Universe

Compliance Today - March 2020
Primer on informed consent

By Elizabeth Cameron, MBA, JD and Tom Ealey, MA, CPA

Elizabeth Cameron (Cameron@alma.edu) is a Professor of Management and Business Law at Alma College in Alma, MI. **Tom Ealey** (ealey@alma.edu) is a Professor of Business Administration at Alma College.

Consent is largely a function of state law, with many common threads weaving through the various statutes. All providers should be well versed in the laws of their state. Medicare regulations also play a role in consent standards.[1]

Protecting the rights of patients is paramount, but compliance with the law also protects providers. There is a significant interest in monitoring compliance with informed consent policies and regulations. Important regulatory and litigation risks exist in the failure of informed consent practices. Compliance efforts must be directed toward ensuring a robust program of informed consent and faithful adherence to organizational standards. How do we discover consent failures? Usually through complaints, regulatory sanctions, and/or litigation. All are best avoided!

Why is this a compliance issue?

Informed consent usually becomes an issue when something has gone wrong. Satisfied patients rarely raise consent issues. When the patient is injured or aggrieved, lawyers get involved, and then practices and policies are questioned. This may include a challenge to consent procedures. A pattern of failure to obtain informed consent may trigger false billing claims or other legal remedies.

Example: *A Michigan physician received consent and provided chemotherapy to hundreds of patients—many of whom he knew did not have cancer. This was done to increase billing and income. The consents were invalid, and the billings were false claims.*[2]

This was an extreme case, but no one responsible for compliance noticed until it was too late. Often consent issues are raised in malpractice actions and add to severe reputational and financial risks. Trust your physicians? Trust but verify.

Protecting the organization and protecting providers is a duty of compliance officers. Given the possible reputation and financial risks, this should be a priority in policy development, training, and documentation.

Defining consent

The Joint Commission defines informed consent as: "...informed consent in medical care is a process of communication between a clinician and a patient [or surrogate] that results in the patient's authorization or agreement to undergo a specific medical intervention."[3]

In longer form, the Commission says:

> Informed consent: Agreement or permission accompanied by full notice about

> the care, treatment or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient either consents to or refuses such a procedure or treatment.[4]

There are two types of consent: implied and express.[5] Implied consent is often appropriate for routine matters. Express consent is absolutely necessary for anything beyond routine.

Example: *Tom calls his primary care office for his annual physical. He arrives for the appointment, signs in, updates his insurance information, follows the instructions of the medical assistant, and is seen by the physician. Tom's actions imply consent.*

Example: *During the course of his physical exam, the physician decides Tom needs knee X-rays, lab work, and an EKG. Express written consent would be appropriate here.*

Obtaining express consent for every patient encounter is perfectly acceptable, as long as the consent is truly informed. Express consent, either oral or written, is a clear expression of intent and consent to receive care. Providers should seek written consent, which is preferred in most situations.

Patients (and surrogates) have, with just a few exceptions, the right to accept or refuse examination and treatment. A refusal of care should only be countermanded under specific unusual circumstances.[6]

Defining "informed"

Giving the marvels of modern medicine how do we define and measure "informed"? How does a person with two college degrees and years of clinical training talk to someone with a high school education or less? How does modern science translate to laymen's terms? How much information is enough, and how much is too little?

These are the necessary components of consent:

- A description of the nature and extent of the service,
- An explanation of the potential benefits,
- An explanation of the risks (e.g., minimal benefits, infection, death),
- An explanation of the alternative courses of action, and
- An explanation of the possible outcomes of doing nothing.

Consider practical consent problems, such as patient (or surrogate) confusion, stress, pain, provider influence (i.e., prejudice toward action), and family drama. All can complicate the process.

Provider duties

Providers should not examine, treat, medicate, perform imaging or lab testing, or perform surgery without informed consent. There are a very few exceptions, such as emergent situations and patient disability. Not only is receiving informed consent critical, but documenting informed consent is very critical. This is not just an individual provider issue—this is an organizational issue.