Webinar: Informed Consent

April 27, 2015  1 – 2:30 p.m. ET

Ever been confused about what standards and guidelines apply to informed consent? This webinar will discuss the current CMS hospital Conditions of Participation (CoPs) and The Joint Commission and DNV Healthcare standards on informed consent requirements. It will include some confusing CMS changes such as having a patient advocate sign the consent form when present even if the patient is competent.

Webinar Objectives

- Recall that the CMS hospital CoP interpretive guidelines has 3 separate sections on informed consent
- Explain that hospitals and critical access hospitals have a separate guideline from CMS on informed consent and they are very different
- Describe the six minimum requirements that are now mandatory to be in the informed consent form for surgery done at a hospital that receives Medicare reimbursement including that the name of the hospital must always be on the form
- Discuss that the CMS and accreditation standards applicable to your facility should be reflected in the hospital’s policies and procedures
- Identify that the medical staff must have a list of procedures and tests that will require an informed consent under federal regulations

Target Audience

CEO, Compliance officer, chief medical officer (CMO) chief nursing officer (CNO), COO, Nurse Educator, Nurses, Nurse Directors, Nurse Supervisors, Nurse Managers, Board Members, Physicians, Medical staff coordinator, patient safety officer, senior leadership, hospital legal counsel, Risk Manager, Chief Risk Officer, PI director, Joint Commission or DNV coordinator, director of health information management, director of anesthesia, OR nurse director, nurses, Patient Safety Officer, Pastoral Care, Patient Advocates, Ethics Committee and others responsible for compliance with hospital regulations, and persons responsible for rewriting policy and procedure on informed consent

Webinar Outline

Introduction to the Hospital CoP Informed Consent Requirements

- CMS interpretive guideline on informed consent for hospitals
- Three sections in hospital CoP
- Update policies and procedures
- Educate staff including medical staff
- Consent from the patient who is not incapacitated and the patient representative
- Consent when the patient is incapacitated
- Patient advocate asked to sign consent even if patient is competent

**Informed Decision Section 1 CMS Hospital CoPs**
- Informed consent as a process
- Right to make informed decisions
- Right to be informed of health care status
- Right to refuse care
- Evaluate patient rights
- Right to delegate right to another for informed decisions
- Surrogate decision makers
- Right to participate in plan of care after discharge
- Right to receive understandable information
- Policies and procedures required
- Survey procedure for surveyor

**Surgical services Section 2 CMS Hospital CoPs**
- Consent form on chart before surgery
- Emergency exception
- Short and long term risks
- Benefits
- Physician professional judgment
- Surgery definition
- Hospital must assure consent process
- Anesthesia consent required
- Surgery consent policy requirements
- Documentation in medical record
- Elements of well-designed consent process
- Risks, benefits, alternatives etc.
- Surgical residents, RNFA, surgical Pas
- Important tasks related to surgery and disclosure
- Surgical resident section
- Moonlighting resident or fellow
- MS must approve list of when consent is required
- Surveyor to interview patients on process
- Medical record review by surveyor

**Medical Records-Section 3 CMS Hospital CoPs**
- Inpatients and outpatient requirement
- Consent on chart prior to surgery
- Minimum elements in informed consent
- Name of hospital on consent form
- Revised witness requirement
- Material risk definition

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• Signature of patient on consent form required
• Additional elements to consider on consent form
• Surveyor review of six charts
• Surveyor procedure

CMS Critical Access Hospital CoPs
• 2 separate sections in CAH manual
• Consent requirements
• Significant surgical tasks
• Consent as a process
• Mandatory and optional requirements

Joint Commission Informed Consent Standards
• Remember state law requirements
• RI.01.03.01 and the EPs
• Written policy requirements
• Surgery and procedures requiring consent must be specified
• Consent as a process
• Risks benefits, and side effects
• Elements not required by CMS
• Exceptions to policy
• Emergency surgery
• Consent on chart required before surgery
• Consent for photography
• TJC tracer on consent

DNV Healthcare Standard on Informed Consent
Research Informed Consent Requirements
Professional Organization Resources on Consent
Additional Resources Slides Provided on:
• AAAHC and AAAASF Standards on Consent
• AOA HCFA Standard on Informed Consent

About the Speaker
Sue Dill Calloway, R.N., M.S.N, J.D. is a nurse attorney and President of Patient Safety and Healthcare Consulting and Education. She was the past VP of Legal Services at a community hospital in addition to being the Privacy Officer and the Compliance Officer. She worked for over 8 years as the Director of Risk Management and Health Policy for the Ohio Hospital Association. She was also the immediate past director of hospital patient safety and risk management for The Doctors Insurance Company in Columbus area for five years. She does frequent lectures on legal and risk management issues and writes numerous publications.

Ms. Calloway has given many presentations locally and nationally to nurses, physicians and attorneys on medical and legal issues. She has authored numerous articles and over 1000 articles and 100 books, including the 2009 Joint Commission Leadership

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