Compliance Update:

Challenged by the CMS Requirements for Informed Consent?
Ensure Compliance with Healthcare’s Most Complex Documentation

Taylor Healthcare Webinar Series
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Webinar Objectives

• Review areas of compliance and mechanisms for surveys and accreditation
• Examine symptoms of non-compliance
• CMS requirements for informed consent
  – Policy
  – Form
  – Process
  – Survey
• Recommendations
  – Location of consent
  – Concurrent surgery and multi-procedure surgery
  – Items not mentioned by CMS
• References
Background - Compliance

Compliance

• Requirements
  – Medicare Conditions of Participation (CoPs)
  – State-specific requirements
  – Other standards
  – Case law
State Law
- Medical Disclosure Panels
- Special Cases
- Emancipated Minors
- Minimum age for mental health consent
- Surrogate and legal representatives


Case Law
- Example: Wisconsin Supreme Court expansion of the duty to disclose diagnostic options that may not be fully supported by the presenting symptoms

Compliance

- Survey/Accreditation Organizations
  - State Survey Agencies
  - CMS Regional Office
  - The Joint Commission
  - DNV
  - HFAP

DNV

- Deeming authority in 2008
- Have accredited almost 500 hospitals
- Integrates ISO 9001 with the Medicare Conditions of Participation
  - Does require ISO 9001 certification
  - Quality focus with emphasis on organizational compliance with policy and procedures

Symptoms of Non-Compliance

Deficient Consent Forms

• 157-hospital study
• Only 26 percent of forms included all of the “basic elements”
  – Description of the procedure
  – Risks
  – Benefits
  – Alternatives

Consent Continues to Pose Problems

- Consent was obtained for an EGD but not the two nasolaryngoscopy procedures that may have resulted in complications that may have contributed to her death
- No consent for observers/photography


Poor Consent Form Execution

- Missing information
- Illegible writing
- Abbreviations
- Version control
- Provider-to-provider variation

Errors and Omissions

- “During a recent CMS survey at XXXXXXXX, the surveyors found a couple deficiencies on 2 documentation items. The surgical consent is a paper form scanned into the record after all signatures are documented. This requires manual dating and timing with the signatures which was missed by the providers on a few cases.”

Lost or Misplaced Consents

- 66 percent of patients had the consent missing from their record at the time of surgery
- Delayed 10 percent of total cases


General Comments

- Our focus will be limited to surgical/treatment consents
  - CMS offers separate guidance on Advance Directives, privacy, restraints, visitation, organ donation, tissue banking
- Information must be specific to the patient
  - *The right to make informed decisions means that the patient or patient’s representative is given the information needed in order to make "informed" decisions regarding his/her care.* Interpretive Guidelines §482.13(b)(2)
- Consent must be executed by the patients in writing
  - *Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.* Interpretive Guidelines §482.24(c)(4)(v)
Policy

- Policy for informed consent must cover the following:
  - Who may obtain the patient’s consent (which providers)
  - Which procedures require informed consent
  - Circumstances for no consent (emergent circumstances)
  - Circumstances for when a patient’s representative may provide consent
  - Content of the form and instructions for completing it
  - The process used to obtain informed consent, including how informed consent is to be documented in the medical record
  - Mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in the case of emergency surgery)

Interpretive Guidelines §482.51(b)(2) – Surgical Services

Policy

- Policy for informed consent must cover the following:
  - If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient’s medical record prior to the surgery
  - Any state-specific requirements

Interpretive Guidelines §482.51(b)(2) – Surgical Services
Form

• A properly executed informed consent form contains the following minimum elements:
  – Name of the hospital
  – Name of the specific procedure(s) or type of medical treatment
  – Name of the responsible practitioner who is performing the procedure or administering the medical treatment
  – Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative
  – Signature of the patient or the patient’s legal representative
  – Date and time the informed consent form is signed by the patient or the patient’s legal representative

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records

Form

• A well-designed informed consent form might also include:
  – Name of the practitioner who conducted the informed consent discussion
  – Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form
  – Indication or listing of the material risks of the procedure or treatment that were discussed
  – Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records
Form

A well-designed informed consent form might also include:

- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

Interpretive Guidelines §482.24(c)(4)(v) – Medical Records

Process

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used
- The indications for the proposed surgery (reason for procedure)
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s clinical judgment
- Treatment alternatives, including the attendant material risks and benefits
- The probable consequences of declining recommended or alternative therapies

Interpretive Guidelines §482.51(b)(2) – Surgical Services
Process

- A well-designed informed consent process would include discussion of the following elements:
  - Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies.
  - Whether qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

Interpretive Guidelines §482.51(b)(2) – Surgical Services

Process

- A well-designed informed consent process would include discussion of the following elements:
  - If residents will perform important parts of the surgery, discussion is encouraged to include the following:
    - That residents will perform portions of the surgery, based on their availability and level of competence.
    - That it will be decided at the time of the surgery which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident’s skill set; and the patient’s condition.
    - That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.
    - Whether, based on the resident’s level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

Interpretive Guidelines §482.51(b)(2) – Surgical Services
Survey

- Review policies and procedures
  - Procedures that require informed consent
  - When procedures may be considered emergent (no consent required)
- Review a minimum of six non-emergent informed consent forms
  - Will ideally review the records of patients who are about to undergo surgery or who are located in a surgical recovery area
- Confirm presence in chart prior to surgery
- Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients’ representatives, to see how satisfied they are with the informed consent discussion prior to their surgery

Interpretive Guidelines §482.51(b)(2) – Surgical Services

Recommendations
Recommendations

- Review your policy against the CMS guidelines
  - If you place elements in your policy – mirror them on the consent form to provide verification of completion
  - Then evaluate your processes against your policy
  - Interview patients (your surveyors will)

Two Ideas

1. Electronic Informed Consent
   - 96 percent of patients preferred procedure-specific electronic consent to traditional fill-in-the-blank consent

2. Employ Teach-Back
   - 575-subject, 7-site randomized controlled trial
   - Improved comprehension and satisfaction
   - Required only 2.6 additional minutes


Recommendations

- Pay special attention to your policies along with disclosure and documentation of:
  - Concurrent/overlapping procedures
  - Use of residents
  - Use of assistive personnel

Concurrent Surgery

- Boston Globe series spurs Senate review and inquiry
- Watch the American College of Surgeons for new guidance

Recommendations

- Automate your consent process to:
  - Establish version control
  - Prevent errors and omissions
  - Ensure that the consent is present in the medical record

Preventable Issues

- Version control
- Consent expiration
- Documentation of an interpreter

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**Sterilization Consent Form PM 316**

The following information is required regarding the sterilization consent form:

- The consent form must be signed by the patient and a witness.
- The patient must be at least 18 years of age.
- The patient must understand the risks and benefits of the procedure.
- The patient must consent to the sterilization procedure.

For more information, please contact your local health department or the Department of Health and Human Services.
Date and Time

- Four specific consent forms are cited as lacking date and time or the time of signature


OR Start Time Delays

- Missing or problematic consents had a negative impact upon OR start times in 46 percent of cases
- Declined to less than 1 percent of cases with implementation of an electronic informed consent process

Recommendations

• Establish policies and procedures for obtaining informed consent outside the walls of your institution:
  – Ensure that your consent documentation process operates seamlessly in remote physician offices

Where to Obtain Consent

• In malpractices cases, alleging inadequate informed consent, consents obtained in the pre-operative holding area, compared to in the surgeon’s office, resulted in significantly higher legal expenses and indemnity payouts
  – $322,000 higher, on average, for the orthopedic procedures studied

Recommendations

- Ensure that you have a policy and process to document consent for multiple procedures.
  - Ensure also that you obtain and document consent for foreseeable or “possible” procedures that may be performed based on intraoperative findings.

Possible Procedures

- When possible procedures can be anticipated, it is best to document those surgical options with specificity rather than relying on an ambiguous, non-specific legal boilerplate.
  - Example: Exploratory Laparotomy with possible Appendectomy and possible Cholecystectomy.
Recommendations

- Pay attention to anesthesia consent – CMS is relatively non-specific in this area
- Add a blank or space to capture surgical site on your consent

Avoiding Errors

- An instance of wrong-patient/wrong-procedure/wrong-site surgery reaches a patient, on average, once per year in a 300-bed hospital

Avoiding Errors

- The most effective mechanism for avoiding wrong-patient/wrong-procedure/wrong-site surgery is verification of the consent form.
  - 30-month study of all hospitals in Pennsylvania


Failure to Verify

- "...the Surgical Fellow proceeded to perform the DIP fusion on the patient's distal middle right finger, instead of the small finger per the Surgical Consent signed by the patient..."

Final Example

- Patient with a femoral neck fracture

Added Two Sections

- Procedure description
- Surgical site
Recommendations

- Employ the consent during the verification of patient, procedure and surgical site
- Do not overlook the benefits of automation to ensure compliance

Questions

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References

• State Operations Manual (Rev. 151, 11-20-15)
  – §482.13 Condition of Participation: Patient's Rights
  – §482.24 Condition of Participation: Medical Record Services
  – §482.51 Condition of Participation: Surgical Services

• Consent to Treatment: A Practical Guide, Fifth Edition
  – Fay Rozovsky, JD, MPH
  – Wolters Kluwer (updated annually, last update 12/07/15)

• Department of Veterans Affairs Policy for Informed Consent
  – VHA Handbook 1004.05
  – December 10, 2014

• iMedConsent.com
  – Slides from this webinar, other presentations, articles, links to references