Maneuvering the Maze of CMS and TJC
Informed Consent: Standards Every Hospital Should Know

Monday,
December 15th, 2014

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Learning Objectives

1. List the 3 sections that contain the CMS hospital CoP interpretive guidelines on informed consent.

2. Explain what the differences are between critical access hospitals and prospective payment system hospitals in CMS CoP interpretive guidelines on informed consent.

3. List the six mandatory requirements that have to be included on the informed consent form for surgery performed at a hospital that receives Medicare reimbursement.

4. Discuss what CMS standards should be reflected in a hospital’s policy and procedure document.

5. Identify the procedures and tests that require informed consent forms according to federal regulations.

6. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.

7. Evaluate compliance requirements and penalties.
Consent Forms Missing in 66% of Surgeries

- OR is expected to work like clockwork
- Study found that consent forms were missing for 66% of surgeries
  - Problem if the timed antibiotics have been started
- This delayed 10% of all surgical procedures
- Cost of lost or misplaced consents cost average hospital $580,000 each year
- Study done by researchers at the prestigious Johns Hopkins University, Aug 2013
Consent Forms Missing in 66% of Surgeries

New Research from Johns Hopkins – The Case of the Missing Consent Form

By Timothy Kelly, MS, MBA

The operating room is one place in a hospital where things are expected to run like clockwork – it is imperative that surgical procedures start on time. When delays occur, the impact can be significant: staff and equipment are underutilized, surgeons become frustrated, patients grow (more) anxious and optimum outcomes may be placed at risk, particularly if the prior administration of medications or antibiotics had been timed to the projected start of a procedure. It is thus alarming that a recent study in JAMA Surgery found that 10 percent of surgical procedures were delayed due to a missing piece of paper – the consent form.[1]

Researchers at the Johns Hopkins University School of Medicine found that consent forms were missing for 66% of surgical patients, which resulted in one out of ten cases being delayed. As a consequence, 43% obtain consent from a patient for whom the form was missing. Also of concern, only 47% of those residents reported that they felt comfortable obtaining consent for major procedures. The study also found that on average, residents spent less time obtaining consent from patients than did attending physicians and that disparity became more pronounced when residents obtained a patient’s consent at the last minute.

Cost of Delays and Patient Dissatisfaction

The problem of lost or misplaced consents is both ubiquitous and extremely costly. It has been estimated that operating room delays resulting from these missing documents cost the average hospital $580,000 each year.[2] Fortunately, the application of technology can virtually eliminate this problem. Ten years ago the Department of Veterans Affairs (VA) implemented an automated informed consent software program that stores signed consent forms directly to the electronic health record – the VA reports that misplaced or lost consent forms have significantly decreased following their adoption of this electronic system.[3]

Inefficiency is only one consequence of a missing consent form. The Hopkins researchers noted that obtaining consent in the hurried environment of the preoperative area may
Which Informed Consent Provision?

- Need to know which standards and guidelines apply to you
- There are usually more than one that apply
- Hospitals that accept Medicare and Medicaid must follow the CMS Hospital CoPs
- There is a separate CoP for Critical Access Hospitals (CAH) and PPS Hospitals
  - Tag 304 and 320
- Every state has a specific state law
Which Informed Consent Provision?

- Separate consent form is required for research that is conducted.

- If facility is accredited by the Joint Commission (TJC) then need to follow that accreditation program’s standard (no longer called JCAHO).
  - DNV Healthcare, CIHQ (Center for Improvement in Healthcare Quality) and AOA Healthcare Facility Accreditation Program also have deemed status from CMS.

- If accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) then need to follow their standards.
Which Informed Consent Provision?

- Same if accredited by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)
- If freestanding ambulatory surgery center there are consent requirements in the CMS Conditions for Coverage (CfC)
- Remember to consider position statements on informed consent from professional organizations
CMS Hospital CoPs

Informed Consent Standards for Hospitals
Informed Consent

- CMS has regulations that all hospitals must follow that accept Medicare reimbursement
- Must follow the hospital CoP for all patients and not just Medicare or Medicaid patients
- CMS takes the federal regulation and adds directions to the surveyors on how to survey
- Called the CMS Interpretive guidelines for the Conditions of Participation (CoPs)
- Has three sections on informed consent
Informed Consent

- All are different so must read together
- Interpretive guidelines and most current available is published February 14, 2014
- CMS PPS hospital manual has three sections on consent (Appendix A)
- CAH (25 bed hospital or less) has two section in Tag C-0304 and C-0320 (Appendix W)
- If CAH has a separate Rehab or Behavioral Health distinct unit and then follow the PPS Hospital CoPs (Appendix A)
Informed Consent 3 Sections in CMS Manual

- **Informed decisions** (Tag A-131 Patient Rights)
- **Medical records** with minimum requirements for consent form (Tag A-465)
- **Surgical services** (Tag A-955)
  - Manuals are all located at a new website at www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
Medicare State Operations Manual
Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.

- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.

- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers.

New website

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State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 103, 02-14-14)

Transmittals for Appendix A

Survey Protocol

Introduction
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing Bed Survey Module

State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev. 90, 08-30-13)
(Rev. 99, 01-31-14)

Transmittals for Appendix W

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Survey Protocol

Introduction
Regulatory and Policy Reference
Tasks in the Survey Protocol
Survey Team
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 - Post-Survey Activities

Regulations and Interpretive Guidelines for CAHs
How to Keep Up with Changes

- First, periodically check to see you have the most current CoP manual.¹
- Once a month go out and check the survey and certification website.²
- Once a month check the CMS transmittal page.³
- Have one person in your facility who has this responsibility.

¹ http://www.cms.hhs.gov/manuals/downloads/som107_AppendicesToC.pdf
² http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
³ http://www.cms.gov/Transmittals
Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Select From The Following Options:

- Show all items

- Show only (select one or more options):
  - Show only items whose [ ] is within the past [ ]
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There are 455 items in this list.
Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

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Transmittals

www.cms.gov/Transmittals/01_overview.asp
Visitation IG Made Changes to Consent

- CMS issued a 34 page memo on interpretive guidelines
  - Issued September 7, 2011 and transmittal issued 12-2-2011
  - It clarified the federal law regarding visitation advance directives
- It also include sections that amended consent, plan of care and advance directives
- It amended tag A-0131 on informed decision and consent
Memorandum Summary

- **President’s Directive:** On April 15, 2010 the President issued a memo concerning hospital visitation and designation of representatives.

- **Clarification of Patients’ Rights Concerning Designation of Representatives:** Hospitals are obligated under certain circumstances to extend patients’ rights to patients’ representatives. The Centers for Medicare & Medicaid Services (CMS) expects hospitals to give deference to patients’ wishes concerning their representatives, whether expressed in writing, orally, or through other evidence. Hospital Appendix A is being revised to clarify the applicable requirements.
Patient Rights Informed Consent

- Discusses patient’s or patient representative’s right to make informed decisions regarding their care
- The first section on informed consent is located in the patient rights chapter
- Final interpretive guidelines
  - Make sure you have the most current edition of the hospital CoP manual
Standard: The patients or their representatives has the right to make informed decisions regarding their care.

This includes the right to be informed of their health status, be involved in the care planning, and can request or refuse treatment.

The right to make informed decisions means the patient is given information in order to be able to make this decision.

This is important to make sure informed consent is given.
The patient must be able to request or refuse treatment.

This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Patient has right to delegate decision making to another person to the degree permitted by state law.

Patient has DPOA but it doesn’t become effective until patient is mentally incompetent.

Competent patient can designate a decision maker (best to get in writing).
Consent & Informed Decisions  A-0131

- Competent patient asks someone to be their representative, orally or in writing, then person must be given information on informed decisions about patient care
  - So both the competent patient is given information along with the personal representative (PR) such as the patient advocate/support person
  - This included getting informed consent from them when required including patient advocate
- CMS states “The hospital must also seek the written consent of the patient’s representative when informed consent is required for a care decision.”
When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the information required to make an informed decision about the patient’s care. The hospital must also seek the written consent of the patient’s representative when informed consent is required for a care decision. The explicit designation of a representative by the patient takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.
Consent & Informed Decisions A-0131

- When patient is incapacitated and has no advance directives in the chart then hospital is expected to accept the assertion of the person claiming to be the PR

- Hospital can not demand any supporting documentation (could do attestation)
  - Except if more than one person shows up claiming to be the PR

- Then have a P&P to resolve this issue

- Hospital is expected to take reasonable steps to determine if they have a PR
When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient’s spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient’s representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the individual the information required to make informed decisions about the patient’s care. The hospital must also seek the consent of the individual when informed consent is required for a care decision. Hospitals are expected to treat the individual as the patient’s representative unless:
If the hospital refuses to let someone be treated as the PR then this must be documented in the medical record along with the specific refusal.

The right to know the diagnosis, prognosis, is afforded so informed decisions and informed consent can be obtained.

CMS has a section in the medical record and surgery section on what is required to be in the consent form.
Patient Rights A-0131

- Patient has right to participate in plan of care
- This includes providing consent to a medical or surgical procedure
- Includes the right to refuse to consent but must be an educated right
- Hospital must establish a process to assure that the patient is given information on health status, diagnosis and prognosis
- Giving informed consent to treatment or surgical procedure is one type of informed decision
Patient Rights

- Extends to the right to be informed in planning for discharge in post acute setting (home health, hospice, long term care)
- CMS requires that a written list be given to patient and documented in chart for LTC and HHC choices
- Hospital must have P&P to assure right to request or refuse treatment
- Policies must address how patient request will be handled
- No obligation to medically unnecessary or inappropriate care
Make Sure Hospital P&P Address:

- Right to make informed decisions and how to assure patient’s ability to exercise this right
- Delegation of patient’s right to representative
- How patients will be involved in their care planning and treatment
- Patient requests for treatment and circumstances in which request can be denied
- Policy must include any state laws on patient rights
Patient has a right to formulate advance directives and to have hospital staff and practitioners follow these directives.

In advance directives, patients can delegate decision making to another person:
- Can be DPOA or mental health care proxy

Patients may also delegate a support person to exercise visitation rights:
- Also referred to as the patient advocate/support person

Designation in the AD takes precedence.
§482.24(c)(2)(v) 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

- Medical record must contain an informed consent for procedures and treatments specified as requiring one

- Medical staff by-laws should address this
Medical Records Requirements

- Consider state laws requiring informed consent such as for invasive procedures
- Consider any federal laws such as informed consent for research
- The list of procedures should be the ones that physicians have privileges to do
- Add new ones to the list as physician request them
- Ones with risks should require a consent form
# List of Procedures

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<td>Cardioversion</td>
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Informed Consent Forms

- Need for **all** surgeries except in emergencies
- All inpatients and outpatients
- For all procedures specified
- Needs to reflect a process
- Form must follow policies
- Must include state or federal requirements
- Must contain 6 minimum requirements (mandatory)
Minimum (Mandatory) Elements Required

- Name of the hospital where the procedure or other type of medical treatment is to take place
- Name of the specific procedure, or other type of medical treatment for which consent is being given
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment
Mandatory Elements Required

- 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
- Same discussion of likelihood and severity
- Signature of patient or representative
- Date and time signed by patient
- Any applicable state law requirements
CMS Well Designed Elements (Optional)

- Hospitals can adopt optional elements
- Therefore, physicians and others practicing in the hospital need to review the hospital’s policy to determine what other elements have been adopted
- Also be aware of any informed consent requirements in the medical staff bylaws or rules and regulations
Optional Elements May Include:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient’s representative
- 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 with the patient or the patient’s representative
Optional Elements May Include:

- 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
Optional Elements May Include:

- Statement, if applicable, that QMP, who are not physicians,

- will perform important parts of the surgery or administration of anesthesia

- and will perform 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.
Survey Procedure

- Verify hospital has assured MS has created a list of procedures and treatments that require consent
- Verify informed consent forms have elements listed as minimum elements
- Compare hospitals standard informed consent form to their policies to make sure consistent
- Make sure any state law requirements are there
Survey Procedure

- These are directions to the surveyor
- Review six medical records for patient undergoing or who have had surgery or procedure or treatment that requires consent
- Verify each medical record has informed consent forms
- Verify each consent form has minimum elements required
Surgical Services  0955

- What does the regulation say?
- Standard: A properly executed informed consent form for the operation must be in the patient’s chart before surgery, except in emergencies
  - Purpose of process is to ensure patient or representative is given information to evaluate a proposed surgery before agreeing to it
  - Discuss short and long term risks
Surgical Services Guidelines

- Benefits to the proposed interventions
- The likelihood of each based on:
  - Clinical evidence
  - Practitioner’s professional judgment
- Informed consent must be in the Medical Record prior to surgery
- Except in case of emergency surgery
- “Surgery” includes any procedure specified by the medical staff and that is listed as a surgery by ACS
Surgical Services

- Hospital must assure practitioner responsible for surgery has obtained informed consent
- Must be in manner consistent with P&P
- Anesthesia consent went from requirement to recommendation but ASA recommends a consent
- Should mandate anesthesia consent for other invasive procedures and surgeries
Hospital Surgical P&P Include:

- Who may obtain the patient’s informed consent?
- Which procedures require informed consent?
  - Have a list approved by the Medical Staff
- The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent
Hospital Surgical P&P Include

- The circumstances when a patient’s representative, rather than the patient, may give informed consent for a surgery
  - Parent, guardian, support person (patient advocate, care partner) or DPOA
- The content of the informed consent 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
Hospital Surgical P&P Include

- Mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery

- If the informed consent form is obtained outside the hospital, how the properly executed form is incorporated into the patient’s medical record prior to the surgery
  - Fax, email, patient or physician can bring form in

- Any other state law requirements on consent
Well Designed Elements (Optional)

- A description of the proposed surgery, including the anesthesia to be used
- Indications for the proposed surgery
- Material risks and benefits for the patient related to the surgery and anesthesia including the likelihood of each
  - Material risks are those with high degree of likelihood but low degree of severity and
  - Low degree of likelihood but high degree of severity
Well Designed Elements (Optional)

- Treatment alternatives, including the material risks and benefits
- The probable consequences of declining recommended or alternative therapies
- Who will conduct the surgical intervention and administer the anesthesia
- Whether anyone else besides operating practitioner will be doing important tasks of surgery
Important Surgical Tasks Include:

- Opening and closing
- Dissecting tissue
- Removing tissue
- Harvesting grafts
- Transplanting tissue
- Administering anesthesia
- Implanting devices and placing invasive lines
Residents Doing Important Parts

Discussion is encouraged to include:

- Resident is doing part based on their availability and level of competence, (except when moonlighting)

- If it is decided at time of surgery which resident will participate

- Their level of participation

- Will be based on knowledge that surgeon has of resident’s skill set

- Patient’s condition
Residents Doing Important Parts

Discussion is encouraged to include:

- If QMP will perform parts of surgery or anesthesia:
  - What types of tasks they will carry out
  - Must be within scope of privileges

- If a resident or QMP is doing important parts you still have to inform the patient but putting it in writing is optional for PPS hospitals
Survey Procedures

- Verify hospital has assured that MS has specified what procedures are considered surgery when IC is needed
- Verify hospital’s informed consent P&P address circumstances when surgery is an emergency
- Surveyor to review at least 6 medical records of surgical patients
- Surveyors look at patients about to go to surgery
- They interview 2 or 3 post surgical patients and see how satisfied they are with the informed consent discussion prior to surgery
Resources

- A site for consent forms that list the risks, and complications, and alternatives of many procedures (Provided by the Queensland Government.)\(^1\)

- They have forms for pediatrics, orthopedics, vascular, urology, surgical, renal, plastic surgery, psychiatry, ophthalmology, maxillofacial, medical imaging, neurosurgery, ear, nose and throat and many more.\(^2\)


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**HERNIA - LAPAROSCOPIC INGUINAL HERNIA REPAIR**

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### A. INTERPRETER/ CULTURAL NEEDS

- An Interpreter Service is required □ yes □ no □
- If yes, is a qualified Interpreter present □ yes □ no □
- A Cultural Support Person is required □ yes □ no □
- If yes, is a Cultural Support Person present □ yes □ no □

### B. CONDITION AND PROCEDURE

The doctor has explained that I have the following condition: *(Doctor to document in patient's own words)*

----------------------------------------------------------------------------------------------------------------------

The following procedure will be performed to the ___________________________ side(s):

*(Doctor to document which side)*

Repair of the hernia (rupture) laparoscopically i.e.

### E. RISKS OF THIS PROCEDURE

- There are some risks/ complications. See patient information sheet- "Laparoscopic Inguinal Hernia Repair" for detailed information about the risks involved. *If you have not been given an information sheet, please ask for one.*

  1. The television method may fail and the surgeon may need to do open surgery.
  2. Damage to large blood vessels, gut or bladder when the sharp trocar and cannula are inserted.
  3. Rarely gas, which is fed into the abdominal cavity, can cause heart and lung complications.
  4. Trouble passing urine after the operation due to spasm of the bladder sphincter.
  5. Swelling of the testicle and scrotum in male patients. Also the penis may show bruising. The testicle may stop making sperm and it may
F. SIGNIFICANT RISKS AND RELEVANT TREATMENT OPTIONS

The doctor has explained any significant risks and problems specific to me, and the likely outcomes if complications occur. The doctor has also explained relevant treatment options as well as the risks of not having the procedure.

(Doctor to document in Medical Record if necessary. Cross out if not applicable.)

G. PATIENT CONSENT

I acknowledge that:

The doctor has explained my medical condition and the proposed procedure. I understand the risks of the procedure, including the risks that are specific to me, and the likely outcomes.

The doctor has explained other relevant treatment options and their associated risks. The doctor has explained my prognosis and the risks of not having the procedure.

I have been given a Patient Information Sheet on Anaesthesia (Version 2: 11/2002).

I have been given a Patient Information Sheet (Version 4: 06/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant

Name of Patient/ Substitute decision maker and relationship

Signature

Date

Substitute Decision Maker Under the Powers of Attorney Act 1998 and/or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision-maker must give consent on the patient's behalf.

H. INTERPRETER'S STATEMENT

I have given a translation in ............................................

(state the patient's language here) of the consent form and any verbal and written information given to the patient/ parent or guardian/ substitute decision maker by the doctor.

Name of Interpreter

Signature

Date

I. DOCTOR'S STATEMENT

I have explained

- the patient's condition
- need for treatment
- the procedure and the risks
- relevant treatment options and their risks
- likely consequences if those risks occur
- the significant risks and problems specific to this patient.

I have given the patient/ substitute decision-maker
### Issue of Low Health Literacy

**Minnesota Informed Consent**

Consent form for surgery or invasive procedure

1. I, [print patient’s name]:
   - Agree that I will have [include both the medical term and patient words]:
   - At [name of facility]:
   - The reason for this procedure is [medical condition]:
   - This will be done or supervised by:
   - My doctor may have help from others. Help could include opening and closing the wound. Help might also include taking grafts, cutting out tissue, implanting devices. I have been told who will help, if known. The key team members that will assist are:
     - Name/title: ___________________________ Critical task: ___________________________
     - Name/title: ___________________________ Critical task: ___________________________
     - Name/title: ___________________________ Critical task: ___________________________

2. I have talked to my doctor or health care team about:
   - What the procedure is and what will happen.
   - How it may help me (the benefits).
   - How it might harm me (the most likely and most serious risks).
   - The long-term effects the procedure might have.
   - My other choices for treatment. The risks and benefits of those choices.

Federal and Minnesota state regulations require additional documentation and consent for hysterectomy and sterilization.²

Hysterectomy - Department of Health and Human Services (DHHS) requires a hysterectomy acknowledgement statement (HAS). Below is a sample HAS. It is not mandatory for the provider to use this sample acknowledgement statement. Any document that the recipient, or her representative, has signed that shows the provider informed the recipient that she would be incapable of reproducing due to the hysterectomy is permissible.

Sample Hysterectomy Acknowledgment Statement
My doctor informed me, both orally and with written materials, that the performance of a hysterectomy would make me sterile (not able to have children).

Signed ___________________________ Date ______________________

Note: If the recipient signs the acknowledgment after the hysterectomy, the acknowledgment must show that the recipient was informed of the consequences of the hysterectomy before the procedure was performed.

Sterilizations - This requires exact language, and a DHHS approved form. This form is required by DHHS/CMS for Medicaid paid sterilizations and must be submitted with the bill. Any alternate form would have to be approved the Secretary of DHHS. The brochures with the specific federal consent form are available at:

² Requirements related to hysterectomy and sterilizations are under Title 42: Public Health Subpart F—Sterilizations § 441.258 Consent form requirements and § 441.256 Additional condition for Federal financial participation (FFP)
CONSENT FOR STERILIZATION

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

■ CONSENT TO STERILIZATION ■

I have asked for and received information about sterilization from _______________________. When I first asked ________________________ for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal Funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED TO DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as _______________________. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on: _______ Month Day Year

I, ________________________, hereby consent of my own

■ STATEMENT OF PERSON OBTAINING CONSENT ■

Before ________________________ signed the name of Individual consent form, I explained to him/her the nature of sterilization operation ________________________, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

Signature of person obtaining consent __________________________ Date __________________________

Facility __________________________

Address __________________________

■ PHYSICIAN’S STATEMENT ■

Shortly before I performed a sterilization operation upon _________________________ on __________________________

name of individual date of sterilization

I explained to him/her the nature of the sterilization operation ________________________.
Critical Access Hospitals (CAH)

Informed Consent Sections
Two Separate CoP Sections
Critical Access Hospitals

- Has a separate manual
- Has two separate sections on informed consent
- Appendix W
- Tag C-0150 to C 0408 and 1000-1002
- Interpretive guidelines updated January 31, 2014 with two changes on locations no longer rule and CAH owned laboratories
- About 232 pages long
- Manual available on-line

CAH Consent Provisions

- Page 16 under patient interviews tells surveyor to question a surgery patient about their knowledge of and consent for the procedure or surgery.

- During document review the surveyor needs to review the medical record to make sure there is an informed consent form on the chart (page 16).
Informed Consent C-0304

- Consent section in Tag 304 and 320
- Different from hospital CoPs
  - We need to get this changed
- Include evidence of properly executed informed consent forms for any procedures or surgical procedures
  - Specified by the medical staff
  - Required by Federal or State law
§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient’s legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.
Informed Consent C-0304

- CAH must maintain a record that has evidence of a properly executed informed consent form

- For any procedure or surgery specified by the MS, state or federal law

- Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.
A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient’s legal guardian
- Name of CAH
- Name of procedure
- Name of practitioner performing the procedure
- Signature of patient or legal guardian
A properly executed consent form contains at least the following (continued):

- **Date and time** consent is obtained
- **Statement that procedure was explained to patient or guardian**
- **Signature of professional person witnessing the consent**
- **Name/signature of person who explained the procedure to the patient or guardian**
Informed Consent C-0304

- Surveyor is to verify that medical staff have specified which procedures and surgeries need a written informed consent.

- Surveyor is to verify that there is a consent form on the chart for procedures required by the CAH policy.

- Surveyor must verify consent forms are properly executed.

- Must make sure all consent forms are signed and dated.
Informed Consent 320

- This includes all inpatients and outpatients
- Patient is informed of who will actually perform the surgery (no ghost surgery)
- Must inform patient if practitioner other than the primary surgeon will perform important parts of the surgical procedure
- EVEN if it is under the primary surgeon’s supervision
Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient’s legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments.
Informed Consent 320

Consent must include:

- Name of patient or their legal guardian
- Name of hospital (CAH)
- Name of specific procedure
- Name of person doing the procedure or important parts of the procedure other than primary surgeon
- Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices and altering tissue
Informed Consent 320

- Nature and purpose of proposed treatment, Risks, consequences if no treatment is rendered, alternative procedures or treatments, probability that proposed procedure would be successful-discussed in text

- Signature of patient or guardian

- Date and time consent obtained

- Statement that procedure was explained to the patient or guardian

- Signature of professional person witnessing the consent

- Name of person who explained procedure
Informed Consent 320

- Must disclose information to patient necessary to make a decision
- It is a process and not a form
- Authorization form signed by a patient who does not understand what he is signing is not informed consent
- Given in language patient can understand
  - Remember issue of low health literacy and use interpreter when indicated and document
TJC Hospital Informed Consent Standards
TJC RI Informed Consent

- Remember CMS CoP provisions on informed consent discussed previously
- Remember your **state law** on informed consent and AO (accreditation organization) standards
- TJC has a standard on informed consent in the patient rights chapter or RI chapter
  - **RI.01.03.01** and **RC.02.01.01**
    - Include all 3 sources in your consent policy
**RC.02.01.01 TJC Consent**

- **Standard:** The MR contains information that reflects the patient’s care

- **EP4** The medical record needs to contain the following:
  - Any informed consent as required by the hospital policy
    - TJC added language at the request of CMS
    - Not called JCAHO anymore
    - See RI.01.03.01
This change was made back in March 2011

The consent form must be in the chart unless it is an emergency

The consent form must be properly executed

It must document the patient’s mutual understanding and agreement for care

Must have a written or electronic signature

If patient unable them documentation of the verbal consent by the patient or surrogate decision maker
A properly executed consent form must contain:

- Documentation of a patient’s mutual understanding of and agreement
- Through written signatures or electronic signature
- Or when a patient is unable to provide a signature
- There must be documentation of verbal agreement by the patient or surrogate decision maker
TJC Informed Consent RI.01.03.01

- **Standard:** The hospital honors the patient’s right to give or hold consent
- This section has a rationale
- Obtaining informed consent presents opportunity to establish a mutual understanding between the patient and the LIP
- It is a process is not merely a signed form
TJC Informed Consent RI.01.03.01

- It considers the patient’s needs and preferences
- It considers compliance with laws and regulations and patient education
- Informed consent process helps patient to participate fully in decisions about their care
- It has 13 elements of performance
- EP 8 & 10 do not apply to hospitals
TJC Informed Consent

- Informed consent is a discussion of:
  - What the procedure is to accomplish
  - Reasonable known risks
  - Alternatives
  - Benefits
  - Prognosis
  - What can happen if the surgery or treatment is refused
There are 13 Elements of Performance but only 11 apply to hospitals:

- EP1 - The hospital has a written policy on informed consent
- EP2 - The policy identifies specific care and treatment that requires an informed consent and this must be consistent with law and regulations
- EP3 - Policy describes exceptions to the rule
  - Such as emergencies then document in the chart
EP4 - Policy describes the process to be followed

EP5 - Describe in policy how to document consent in the medical record
  - Form and document in the progress notes

EP6 - Policy describes when a surrogate decision maker can give the informed consent (see RI.01.02.01 EP6)
  - If the patient is unable to make decisions about care, then it is made by surrogate decision maker
EP 7 - Consent process includes a discussion about the patient’s proposed care, treatment and services.

EP 9 - Process includes a discussion about potential benefits, risks, and side effects, likelihood of achieving the patient’s goals and any potential problems that might occur during recuperation.

EP 11 - Process includes a discussion of the reasonable alternatives to the patient’s proposed care, risks, benefits, and side effects of the alternatives.

- Includes the risks of not having the proposed treatment.
EP12 - Informed consent process includes a discussion about any circumstance under which information about the patient must be disclosed or reported

- Examples: mandatory reporting requirements for HIV, TB, viral meningitis, and other diseases to CDC or state department of health

EP13 - Consent is obtained in accordance with the hospital policy and processes

- RC.02.01.01 EP 4 requires the medical record to contain evidence of informed consent
EP 6 When a patient is unable to make decisions about his or her own care

The hospital involved a surrogate decision maker in making these decisions

An example would be a DPOA in a patient who is incapacitated or a legal guardian, a mental health proxy for a patient who is incapacitated on a behavioral health unit, or the parent of a five year child
RI.01.03.03 Consent for Photography

- TJC has a standard that requires the hospital to honor the patient’s right to give or withhold informed consent
- To produce or use recordings, films, or other images of the patient
- For purposes other than his or her care
- There are 7 elements of performance
- RI.01.03.05 document research in consent form and 8 EPs
Sample Consent Form for Photography

- The American Health Information Management Association (AHIMA)
- has a practice brief on Patient Photography, Videotaping and other Imaging\(^1\)

\(^1\) http://library.ahima.org/xpedio/groups/public/documents/ahima/bok2_000585.hcsp?dDocName=bok2_000585
Sample Consent for Photography/Videotaping (For Media or Educational Purposes)

Patient’s Name: __________________________

Identification Number: _______________________

I hereby give my consent to have photographs, videotaped images, or other images made of myself or my family member and/or consent to interviews with a member of the news media or a representative of (name of organization). I understand and agree that these images may be used by the news media or by (name of organization) for the purpose outlined below.

Signature of Patient or Legal Representative     Date     Signature of Witness     Date
Official Publication of Joint Commission Requirement

Clarification of Documentation Requirement for Informed Consent

Applicable to Hospitals and Distinct Part Units in Critical Access Hospitals

Effective Immediately

Element of Performance for Standard RC.02.01.01

C 4. As needed to provide care, treatment, and services, the medical record contains the following additional information:

- Any advance directives (See also RI.01.05.01, EP 11)
- Any informed consent, when required by hospital policy (See also RI.01.03.01, EP 13)

Note: The properly executed informed consent is placed in the patient’s medical record prior to surgery, except in emergencies. A properly executed informed consent contains documentation of a patient’s mutual understanding of and agreement for care, treatment, or services through written signature, electronic signature, or when a patient is unable to provide a signature, documentation of the verbal agreement by the patient or surrogate decision maker.

- Any records of communication with the patient, such as telephone calls or e-mail
- Any patient-generated information
NQF 34 Safe Practices

- Safe Practice 5 addresses informed consent
- Need to make sure that patients understand the proposed treatment and complications
- Consent is an essential part of healthcare
  - Consent is a process
  - Need to have shared decision making
SAFE PRACTICE 5:
INFORMED CONSENT

The Objective
Ensure that patients, and, when appropriate, families and legal guardians, understand the proposed treatment and its potential complications.

The Problem
Obtaining informed consent is an essential part of the healthcare process and is, in fact, a process rather than a single act or event. It is a process of communication between the patient and healthcare provider that results in the patient’s agreement to undergo a specific medical intervention. Informed consent can be plainly described as the learned choice made by a patient. [Plawecki, 2009] The process may result in the execution of a written informed consent document. Informed consent is imperative before the undertaking of any major procedure, including, but not limited to, surgery and other invasive procedures. The primary goal of informed consent is to ensure that patients are fully aware of the treatment options available to them, the potential benefits and risks associated with each option, and the alternatives, including the possibility of no treatment or alternative treatments. This information is crucial for patients to make informed decisions about their healthcare.

It has been shown that more than two-thirds of patients in the United States do not receive any written information about their condition from their physicians. Other studies have shown that up to 75 percent of written consent forms are incomplete. [Shojania, 2001] Because an estimated 90 million adults in the United States have limited health literacy, [IOM, 2004] policies should be implemented to ensure the use of clear informed consent documents that most patients and their families can easily understand. [Denham, 2008a; Shaw, 2009]

Communication failures between patients and healthcare providers are at the root of systems failures and human errors that lead to harm, [Denham, 2008b; Levinson, 2008] but the severity of these failures is not known. Applicants may understand only 30 to 81 percent of information in standard consent forms. [Kripalani, 2008] Informed consent is a critical healthcare process, both clinically, to provide patients with vital information, and ethically, to preserve patient autonomy. A study in the Archives of Surgery examined 540 consent forms in 157 hospitals. Only 26 percent of them addressed the four key elements of informed consent: benefits of treatment, risks, alternatives, and patient choices. 

NQF 34 Safe Practices

- The frequency in which patients do not receive an appropriate consent is of great concern.
- Studies have shown that more than 2/3 of patients do not receive any written information about their condition from their physician.
- Studies show that up to 75% of written consents are incomplete (Shojania, 2001).
- 90 million Americans have low health literacy so make sure you use a clear consent form (Denham 2008, Shaw, 2009).
NQF 34 Safe Practices

- Patients only understand about 30 to 81% of information in a standard consent form (Kripalani, 2008)

- A study in the Archives of Surgery examined 540 consent forms in 157 hospitals
  - Only 26 percent of them addressed the four key elements of informed consent:
    - benefits of treatment, risks, alternatives, and educational information. [Bottrell, 2000]
  - Use teach back
Research

There may be additional regulations for facilities doing human subject research
Research

- US Dept of Health and Human Services (HHS) and several other federal agencies, such as Dept of Education, and the National Science Foundation

- Have regulations on research which are commonly referred to as the common rule

- To protect human subjects involved in research

- Institutional Review Boards (IRB) reviews research proposals even if informed consent is obtained, IRB can waive consent requirement

- See Title 46 Protection of Human Subjects at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46
PROTECTION OF HUMAN SUBJECTS

[PDF 215 KB]

***

Revised June 23, 2005
Effective June 23, 2005

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Subpart A --

Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101
46.102
46.103
46.104-
46.105
46.107

To what does this policy apply?
Definitions.
Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.
[Reserved]
IRB membership.
§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
Sample Informed Consent Form

Consent Form

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

To be in this study, sign this document.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?
§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and, in the judgment of the IRB, it is not feasible to obtain a signed consent form.
Research Consent

- Research investigator needs informed consent from research subject
- Must be in plain language
- Must include a statement that the study involves research
- Explanation of the purpose of the research
- Expected duration of the subject’s participation
- Description of procedures to be followed
- Identification of any procedure considered to be experimental
Research Elements of Consent

- Description of any reasonable foreseeable risks or discomforts to the subject
- Disclosure of any benefits to the subject and others which may be expected
- Disclosure of appropriate alternative procedures or courses of treatment
- Statement to which confidentiality of records identifying the subject will be maintained
Research Elements of Consent Cont.

- Contact information for answers to questions about the research
- Also to include information on patient’s rights in case of a research related injury
- Statement that participation is voluntary and refusal to participate involves no penalty or loss of benefits
- Subject can discontinue participation at any time without penalty or loss of benefits
Office for Human Research Protections (OHRP)

OHRP Informed Consent Frequently Asked Questions

These FAQs provide guidance that represents OHRP's current thinking on these topics and should be viewed as recommendations, unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

Commonly Used Abbreviations

CFR — Code of Federal Regulations
FDA — Food and Drug Administration
FWA — Federalwide Assurance
HHS — Health and Human Services
IEC — Independent Ethics Committee
IRB — Institutional Review Board
| Question 3: | What are the basic elements of informed consent? |
| Question 4: | What additional information might be appropriate to provide during the consent process? |
| Question 5: | Can consent or parental permission ever be “passive” or “implied”? |
| Question 6: | What does it mean to minimize the possibility of coercion or undue influence? |
| Question 7: | When does compensating subjects undermine informed consent or parental permission? |
| Question 8: | Can non-financial enrollment incentives constitute undue influence? |
| Question 9: | What constitutes coercion or undue influence when students are involved in research in a college or university setting? |
| Question 10: | What constitutes coercion or undue influence when employees are the subjects of research? |
| Question 11: | Should the initial consent or parental permission procedure ever be repeated or supplemented? |
| Question 12: | How far in advance of research participation can consent be obtained? |
| Question 13: | Can records or databases be reviewed to identify potential subjects without obtaining informed consent or parental permission? |
| Question 14: | How can the consent and parental permission processes be designed to facilitate understanding? |
| Question 15: | Can an electronic signature be used to document consent or parental permission? |
| Question 16: | Is a faxed copy of the signed consent or parental permission form acceptable to document informed consent? |
| Question 17: | Who must sign the informed consent or parental permission document? |
| Question 18: | Do signatures on consent forms have to be dated? |
| Question 19: | Who can be a legally authorized representative (LAR) for the purpose of providing consent on behalf of a prospective subject? |
AHRQ Toolkit to Facilitate Consent

- AHRQ toolkit to facilitate the process of obtaining informed consent
- Also information on the HIPAA authorization for potential research subjects
- Available at http://www.ahrq.gov/fund/informedconsent/
- Changes to HIPAA privacy, security, HITECH and GINA effective September 23, 2013
The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research

The Agency for Healthcare Research and Quality (AHRQ) has developed the Informed Consent and Authorization Toolkit for Minimal Risk Research to facilitate the process of obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from potential research subjects. This toolkit contains information for people responsible for ensuring that potential research subjects are informed in a manner that is consistent with medical ethics and regulatory guidelines.

Select to download print version PDF File (300 KB). PDF Help.

Contents

Background
Why a Toolkit?
Development of This Toolkit
Informed Consent, HIPAA Authorization, and Adult Health Literacy
How To Improve Informed Consent and Authorization
Improving the Process
Adopting New Processes and Documents in Your Institution
Improving the Informed Consent and Authorization Process
Using the Tool for Researchers’ Certification of Consent and Authorization
Improving the Forms
Sample Documents for Informed Consent and HIPAA Authorization (English and Spanish versions)
Adapting and Testing AHRQ Sample Documents
Regulatory Requirements
Resources
Other Resources From the Department of Health and Human Services
References

AHRQ Publication No. 09-0193-LEF
Current as of September 2009
Guidance for Sponsors, Investigators, and Institutional Review Boards

Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c)

(Small Entity Compliance Guide)

www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm
Research References


 Office for Civil Rights. “Medical Privacy—National Standards to Protect the Privacy of Personal Health Information.” Section “Research”¹


¹ www.hhs.gov/ocr/hipaa/privacy.html
Standards from Professional Organizations

Does your professional organization have any practice briefs or guidelines on informed consent?
Professional Organizations

- Sometimes have good samples, practice briefs or guidelines on informed consent
- This can be helpful to healthcare providers
- Most are now available on the Internet
Standards, Guidelines, Statements and Other Documents

ASA Standards, Guidelines and Statements provide guidance to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. They are not intended as unique or exclusive indicators of appropriate care. The interpretation and application of Standards, Guidelines and Statements takes place within the context of local institutions, organizations and practice conditions. A departure from one or more recommendations may be appropriate if the facts and circumstances demonstrate that the rendered care met the physician’s duty to the patient.

Standards provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.

Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert opinion, open forum commentary, and clinical feasibility data.

Statements represent the opinions, beliefs, and best medical judgments of the House of Delegates. As such, they are not necessarily subjected to the same level of formal scientific review as ASA Standards or Guidelines. Each ASA member, institution or practice should decide individually whether to implement some, none, or all of the principles in ASA statements based on the sound medical judgment of anesthesiologists participating in that institution or practice.

See also: Practice Parameters

Recommendations and Clinical Management Tools - ASA Committee
Anesthesia Care Team, The (2009)
Anesthesia Consultation Program (2008)
Basic Anesthetic Monitoring, Standards for (Effective July 1, 2011)
Clinical Privileges in Anesthesiology, Guidelines for Delineation of (2008)
Conflict of Interest, Statement on (2008)
Continuing Medical Education in Anesthesiology, Guidelines for Minimally Acceptable (2011)
Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (2009)
Critical Care and Trauma Medical Services, Statement of Principles (2011)
Critical Care by Anesthesiologists, Guidelines for the Practice of (2009)
Distinguishing Monitored Anesthesia Care From Moderate Sedation/Analgesia (Conscious Sedation) (2009)
Documentation of Anesthesia Care (2008)
Consent for Anesthesia Services

I, ________________________________, acknowledge that my doctor has explained to me that I will have an operation, diagnostic or treatment procedure. My doctor has explained the risks of the procedure, advised me of alternative treatments and told me about the expected outcome and what could happen if my condition remains untreated. I also understand that anesthesia services are needed so that my doctor can perform the operation or procedure.

It has been explained to me that all forms of anesthesia involve some risks and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected severe complications with anesthesia can occur and include the remote possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death. I understand that these risks apply to all forms of anesthesia and that additional or specific risks have been identified below as they may apply to a specific type of anesthesia. I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, his or her preference, as well as my own desire. It has been explained to me that sometimes an anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia.

<table>
<thead>
<tr>
<th>General Anesthesia</th>
<th>Expected Result</th>
<th>Total unconscious state, possible placement of a tube into the windpipe.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Technique</td>
<td>Drug injected into the bloodstream, breathed into the lungs, or by other</td>
</tr>
<tr>
<td><strong>General Anesthesia</strong></td>
<td><strong>Expected Result</strong></td>
<td>Total unconscious state, possible placement of a tube into the windpipe.</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Technique</strong></td>
<td>Drug injected into the bloodstream, breathed into the lungs, or by other routes.</td>
<td></td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Spinal or Epidural Analgesia/Anesthesia</strong></th>
<th><strong>With</strong></th>
<th><strong>Without</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected Result</strong></td>
<td>Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside the spinal canal.</td>
<td></td>
</tr>
<tr>
<td><strong>Technique</strong></td>
<td>Drug injected near nerves providing loss of sensation to the area of the operation.</td>
<td></td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Major/Minor Nerve Block</strong></th>
<th><strong>With</strong></th>
<th><strong>Without</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected Result</strong></td>
<td>Temporary loss of feeling and/or movement of a specific limb or area.</td>
<td></td>
</tr>
<tr>
<td><strong>Technique</strong></td>
<td>Drug injected near nerves providing loss of sensation to the area of the operation.</td>
<td></td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Intravenous Regional</strong></th>
<th><strong>Expected Result</strong></th>
<th>Temporary loss of feeling and/or</th>
</tr>
</thead>
</table>
Informed consent

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. (For more information about ethical obligations, see the AMA's Code of Medical Ethics, contained in the AMA PolicyFinder. Providing the patient relevant information has long been a physician's ethical obligation, but the legal concept of informed consent itself is recent.
II. RELATION OF THE SURGEON TO THE PATIENT

A. Informed Consent
Informed consent is more than a legal requirement. It is a standard of ethical surgical practice that enhances the surgeon/patient relationship and that may improve the patient's care and the treatment outcome. Surgeons must fully inform every patient about his or her illness and the proposed treatment. The information must be presented fairly, clearly, accurately, and compassionately. The surgeon should listen carefully to understand the patient's feelings and wishes and should answer all questions as accurately as possible. The informed consent discussion conducted by the surgeon should include:

1. The nature of the illness and the natural consequences of no treatment.
2. The nature of the proposed operation, including the estimated risks of mortality and morbidity.
3. The more common known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and post hospital convalescence.
4. Alternative forms of treatment, including nonoperative techniques.

The surgeon should not exaggerate the potential benefits of the proposed operation nor make promises or guarantees. For minors and incompetent adults, parents or legal guardians must participate in the informed consent discussion and provide the signature for elective operations. Any adequately informed, mentally competent adult patient can refuse any treatment including operation. When mentally incompetent patients or the parents (guardians) of minors refuse treatments jeopardizing the patient's best interest, the surgeon can request legal assistance.
A risk calculator that calculated the surgical complication risk based on age, weight, blood pressure, smoker, drug abuse history, diabetes etc.

Initially used by heart surgeons
Now being developed for other surgical specialties
ACS introduced calculators for surgery of the colon and pancreas
Now designing tools for 18 other procedures such as gastric bypass, hernia repair, and prostate surgery
ACS has a surgical risk calculator to give physicians valuable information before scheduling elective surgeries.

- Estimates the chance of an unfavorable outcome such as a complication or death
  - Risk percentages are only estimates

- Looks at up to 22 pre-op risk factors

- Estimates outcomes for more than 1,500 procedures
  - Used data collected from nearly 400 hospitals and 1.4 million patients to develop the calculator
Optimizing ACS NSQIP Modeling for Evaluation of Surgical Quality and Risk: Patient Risk Adjustment, Procedure Mix Adjustment, Shrinkage Adjustment, and Surgical Focus

Mark E. Cohen, PhD, Clifford Y. Ko, MD, MS, MSHS, FACS, Karl Y. Bilimoria, MD, MS, Lynn Zhou, PhD, Kristopher Huffman, MS, Xue Wang, PhD, Yaoming Liu, PhD, Kari Kraemer, PhD, Xiangiu Meng, MS, Ryan Merkow, MD, MS, Warren Chow, MD, MS, Brian Matei, MA, Karen Richards, BA, Amy J. Hart, BS, Justin B. Dimick, MD, MPH, Bruce L. Hall, MD, PhD, MBA, FACS

Received 18 February 2013; accepted 26 February 2013; published online 29 April 2013.

Abstract

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) collects detailed clinical data from participating hospitals using standardized data definitions, analyzes these data, and provides participating hospitals with reports that permit risk-adjusted comparisons with a surgical quality standard. Since its inception, the ACS NSQIP has worked to refine surgical outcomes measurements and enhance statistical methods to improve the reliability and validity of this hospital profiling. From an original focus on controlling for between-hospital differences in patient risk factors with logistic regression, ACS NSQIP has added a variable to better adjust for the complexity and risk profile of surgical procedures (procedure mix adjustment) and stabilized estimates derived from small samples by using a hierarchical model with shrinkage adjustment. New models have been developed focusing on specific surgical procedures (eg, “Procedure Targeted” models), which provide opportunities to incorporate indication and other procedure-specific variables and outcomes to improve risk adjustment. In addition, comparative benchmark reports given to participating hospitals have been expanded considerably to allow more detailed evaluations of performance. Finally, procedures have been developed to estimate surgical risk for individual patients. This article describes the development of, and justification for, these new statistical methods and reporting strategies in ACS NSQIP.

Abbreviations and Acronyms: ACS, American College of Surgeons, CPT, Current Procedural Terminology, O/E, observed to expected ratio, OR, odds ratio, SAR, semi-annual report, VA, Veterans Affairs, VASQIP, Veterans Affairs Surgical Quality Improvement Program

www.journalacs.org/article/S1072-7515(13)00187-7/abstract
The Surgical Risk Calculator  ACS  NSQIP

Enter Patient and Surgical Information

Procedure

http://riskcalculator.facs.org/PatientInfo/PatientInfo

Begin by entering the procedure name or CPT code. You may also search using two words (or two partial words) by placing a '+' in between, for example: "cholecystectomy+cholangiography"

Reset All Selections

Please enter as much of the following information as you can to receive the best risk estimates. A rough estimate will still be generated if you cannot provide all of the information below.

Age Group
- Under 65 years

Sex
- Female

Functional status
- Independent

Emergency case
- No

ASA class
- I - Healthy patient

Wound class
- Clean

Diabetes
- None

Hypertension requiring medication
- No

Previous cardiac event
- No

Congestive heart failure in 30 days prior to surgery
- No

Dyspnea
- None

Current smoker within 1 year
- No

History of severe COPD
- No

Dialysis
- No

Acute Renal Failure
- No

BMI Calculation
- Height (in)
- Weight (lbs)
The End!  Questions???

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- Board Member
  Emergency Medicine Patient Safety Foundation
- 614 791-1468
- sdill1@columbus.rr.com
  - Additional slides DNV, AOA, ASCs etc.
DNV Healthcare

Consent Standards
DNV Healthcare

- Has deemed status with CMS for hospitals
- Newest guy on the block
- DNV Standards available on their website¹
  - 146 pages of standards
- Patient Rights or PR 4 on informed consent on page 96

¹ www.dnv.com
PR.4 INFORMED CONSENT

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

Interpretive Guidelines:

All patients receiving either inpatient and outpatient care must complete an informed written consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations. In the event of a medical emergency, the hospital is not required to obtain a written consent, but timely efforts to obtain an informed written consent from the patient's authorized representative.

The procedures/treatments which will require the hospital to obtain patient written consent will at least include: high-risk procedures (including blood transfusions); sedation; participation in research projects; and, filming or videotaping.

Definition elements: Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations of risks, benefits and alternatives, needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform planned surgical interventions. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon’s supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient’s legal guardian;
- Name of hospital;
- Name of specific procedure(s) or medical treatment;
A properly executed informed consent for surgery shall be in the patient’s medical record before surgery (SS.4).

The hospital must ensure that there is a proper written consent form for the surgical procedure that is signed by the patient or their representative.

Only exception is an emergency.
DNV Consent Form Must Include:

- Name of patient
- Name of hospital
- Name of specific procedure or treatment
- Name of practitioner performing the procedure
- Risk
- Alternative procedures, treatments or therapies
DNV Consent Form Must Include:

- Signature of the patient or legal representative
- Date and time consent form signed
- Signature of the witness
- Name of the person who explained the procedure to the patient or guardian
- Statement that the procedure or treatment was explained to the patient including benefits, risks, and alternatives
DNV Consent Form Must Include:

- Description of the proposed surgery (SS.4)
- Anesthesia to be used
- An explanation of the nature and purpose of the proposed procedures
- Risks and consequences of the procedures
- The probability that the proposed procedure will be successful
- Alternative methods of treatment (if any) and their associated risks and benefits
DNV Healthcare

- Patient is informed as to who will do the surgery
- If practitioner other than the primary surgeon will perform important components of the procedure the patient must be notified
- Identity of others must be disclosed even if working with surgeon (RNFA, Surgical PA, surgical resident, etc.)
Informed Consent Policy Must Include:

- Who may obtain the patient’s informed consent
- Which procedures require informed consent
- The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent
- The circumstances when a patient’s representative, rather than the patient, may give informed consent for surgery
Informed Consent Policy Must Include:

- The content of the informed consent form and instructions for completion
- The process used to obtain informed consent
- How the 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 medical record prior to surgery (except in an emergency)
- If done outside of the hospital then how to get it into the medical record prior to surgery
American Osteopathic Association

Consent Standards
AOA Consent Form Must Include:

1. Name of patient
2. Name of hospital
3. Name of procedure or other type of medical treatment for which consent is being given
4. Name of the responsible practitioner who is performing the procedure or administering the medical treatment
AOA Consent Form Must Include:

5. 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;

- (Material risks could include risks with a high degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner’s professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)

6. Alternative procedures and treatments
Freestanding ASC
Conditions for Coverage CfC
CFC

- New CFC became effective May 18, 2009 and revised several times since then

- CMS website will always display most current version at [www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf) and look under appendix L

- ASCs must meet these in order to get paid for taking care of Medicare patients

- Hospital elects to operate as a department of the hospital (CoPs) or decides to be paid as a ASC (CFC)
State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

(Rev. 99, 01-31-14)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol
Introduction
Regulatory and Policy References
Tasks in the Survey Protocol

Task 1 – Off-Site Survey Preparation
Task 2 – Entrance Activities
Task 3 – Information Gathering/Investigation
Task 4 – Preliminary Decision Making and Analysis of Findings
Task 5 – Exit Conference
Task 6 – Post-Survey Activities

Part II - General Provisions and Definitions; General Conditions and Requirements

§416.2 - Definitions
§416.25 Basic Requirements

Specific Conditions for Coverage

§416.40 Condition for Coverage: Compliance With State Licensure Law

ASC Interpretive Guidelines

- Revised the CFCs so changed the interpretive guidelines
- Added survey procedures and renumbered the tag numbers and 167 pages which includes infection control surveyor worksheet (Q tag numbers 0001-0267)
State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers
(Rev. 76, 12-22-11)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol

Introduction

Regulatory and Policy References

Tasks in the Survey Protocol

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Task 6 – Post-Survey Activities

Part II - General Provisions and Definitions; General Conditions and Requirements
§416.2 - Definitions
§416.25 Basic Requirements

Specific Conditions for Coverage
§416.40 Condition for Coverage: Compliance With State Licensure Law
§416.41 Condition for Coverage: Governing Body and Management
Informed Consent Elements

- Description of the proposed surgery including the anesthesia to be used
- Indications for surgery
- Material risks and benefits for surgery and anesthesia including likelihood of each
- Treatment alternatives with material risk and benefit
Informed Consent Elements

- Who will do the surgery and give anesthesia?
- If any other physician or QMP will do important parts of the surgery
- Important parts include opening, closing, harvesting grafts, dissecting or removing tissue, transplanting tissue, administering anesthesia, implanting devices and placing lines
Pg 79 of the manual under operative and invasive services

Pg 90 informed consent definition in the glossary

- **Informed Consent**: A document signed by the patient or surrogate decision maker indicating that he/she has been made aware of the nature, benefits, risks, and alternatives of a treatment or procedure.

- Discusses when the patient is not competent and has a DPOA the consent is from the DPOA or designate person (guardian)
- The hospital must seek the informed consent of the patient’s representative when consent is required.
- The express designation in the advance directive takes precedence over any no-designated relationship.
- People not involved with the patient’s care can not be present without consent.
- Can not disclose patient information without the consent of the patient.
- Patient need properly executed informed consent for treatments and procedures specified by MS.
Need consent of patient to use family to interpret

Informed consent needed before surgery or any invasive procedure

Hospital must have and follow an informed consent policy

Policy must include the following: who can obtain the consent, which procedures require consent, emergency doctrine, content of the consent form, process to get consent, mechanisms to make sure it is properly executed
Informed consent must be obtained

It must be in the medical record before surgery or the procedure

Practitioner responsible for the procedure must provide consent according to the P&P

Must follow any state specific requirements for informed consent
Accreditation Association for Ambulatory Health Care, Inc.

Accreditation Handbook for Ambulatory Healthcare
AAAHC Consent Standards

- Located on five different pages in manual
- Chapter 9 on anesthesia services requires the informed consent of the patient or their representative before the procedure is performed
- One consent form can be used (anesthesia and surgery) to meet requirements
- Chapter 10 on Surgical and Related Services says informed consent of patient or representative is obtained before the procedure is performed
AAAHC Consent Standards Cont.

- Chapter 12 on Dental Services also require the informed consent of the patient and it must be documented in the medical record prior to the procedure.

- Chapter 18 on Radiation Oncology Treatment Services says must have signed informed consent prior to the treatment.

- Chapter 22 on Research Activities requires research patients are given an informed consent and in a language that is spoken by him or her and is obtained by an adequate and appropriate method (issue of healthcare literacy).
American Association for Accreditation of Ambulatory Surgery Facilities, Inc

AAAASF Consent Standards
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- Medical Records: an informed consent is routinely obtained which specifically authorizes the surgeon, by name, to perform surgery.
- It names or describes the operative procedure.
- Alternatives, expectations, risks, and complications, are discussed with the patient and documented.
AAAASF Consent Standards Cont.

- The informed consent form provides consent for administration of anesthesia or sedatives
- Under the direction of the surgeon, CRNA, or anesthesiologist
AOA HFAP

- The American Osteopathic Association has a program for deemed status by CMS for hospitals
- Much like TJC and DNV Healthcare
- Called HFAP or the Healthcare Facilities Accreditation Program
- Section 10.01.15 requires medical record to have a properly executed informed consent
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Thank you for attending!!

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