

Keeping you "in the know" in the ASC industry







Regulations and Standards: CMS

CMS: PATIENT RIGHTS

416.50(e) Standard: Exercise of rights and respect for property and person

- 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;
 - 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. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
 - Treatment alternatives, including the attendant material risks and benefits;



Regulations and Standards: CMS

CMS: PATIENT RIGHTS

416.50(e) Standard: Exercise of rights and respect for property and person

- A well-designed informed consent process would include **discussion** of the following elements:
 - The probable consequences of declining recommended or alternative therapies;
 - Who will conduct the surgical intervention and administer the anesthesia;
 - Whether physicians other than the operating practitioner will be performing important tasks related to the surgery, in accordance with the ASC's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
 - Whether, as permitted by State law, 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 ASC.



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Regulations and Standards: AAAHC

AAAHC

9.E, 10.I.J Properly executed informed consent(s) was (were) obtained prior to anesthesia administration and pre-operatively. One consent form may be used to satisfy the requirements of these two Standards.

- Documentation is present to demonstrate that the following have been **discussed** with the patient:
 - a. The necessity or appropriateness of the proposed procedure or surgery.
 - b. Alternative treatment techniques.
- The clinical record demonstrates that the patient's written consent, or that of the patient's representative, was obtained before the surgery or procedure was performed.



















CACI 532. Informed Consent - Definition

A patient's consent to a medical procedure must be "informed." A patient gives an "informed consent" only after the [insert type of medical practitioner] has adequately explained the proposed treatment or procedure. A [insert type of medical practitioner] must explain the likelihood of success and the risks of agreeing to a medical procedure in language that the patient can understand. A [insert type of medical practitioner] must give the patient as much information as he/she needs to make an informed decision, including any risk that a reasonable person would consider important in deciding to have the proposed treatment or procedure, and any other information skilled practitioners would disclose to the patient under the same or similar circumstances. The patient must be told about any risk of death or serious injury or significant potential complications that may occur if the procedure is performed. A [insert type of medical practitioner] is not required to explain minor risks that are not likely to occur.

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Elements Required for Consent

- Explanation of proposed treatment or procedure
- Explanation of the risks, benefits, and alternatives
 - In language the patient/patient rep can understand
 - Disclosure of any serious risk of injury
 - Disclosure of any risk of death
 - Disclosure of risks SOC community require
 - Generally not required to disclose "minor" risks not likely to occur
 - Generally <u>not</u> required to disclose alternative treatments that not recommended for that patient

PROGRESSIVE SURGICAL SOLUTIONS

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Understanding Lack of Informed Consent vs. Battery

LACK OF INFORMED CONSENT

- Patient consented to the particular procedure, but wasn't provided enough info to be "informed"
 - Example: agreed to R knee surgery, not told of risk of infection, gets infection following right knee surgery

BATTERY (2 SCENARIOS)

- Patient never consented to the procedure done – e.g., patient agreed to R knee, you did L
- "Conditional consent"- e.g., patient only agreed to fiberoptic intubation



CACI 533. Failure to Obtain Informed Consent Essential Factual Elements

Plaintiff claims that Defendant was negligent because he/she performed a medical procedure on Plaintiff without first obtaining his/her informed consent. To establish this claim, Plaintiff must prove all of the following: 1. That Defendant performed a medical procedure on Plaintiff; 2. That Defendant did not disclose to Plaintiff the important potential results and risks of, and alternatives to, the medical procedure; 3. That a reasonable person in Plaintiff's position would not have agreed to the medical procedure if he or she had been adequately informed; and 4. That Plaintiff was harmed by a result or risk that Defendant should have explained.



CACI 530A. Medical Battery

Plaintiff claims that [name of defendant] committed a medical battery. To establish this claim, Plaintiff must prove all of the following: 1. That Defendant performed a medical procedure without Plaintiff's consent; [or] 1. [That Plaintiff consented to one medical procedure, but Defendant performed a substantially different medical procedure;] 2. That Plaintiff was harmed; and 3. That Defendant's conduct was a substantial factor in causing Plaintiff's harm. A patient can consent to a medical procedure by words or conduct.



CACI 530B. Medical Battery

<u>Conditional Consent</u> Plaintiff claims that Defendant committed a medical battery. To establish this claim, Plaintiff must prove all of the following: 1. That Plaintiff consented to a medical procedure, but only on the condition that [describe what had to occur before consent would be given]; 2. That Defendant proceeded without this condition having occurred; 3. That Defendant intended to perform the procedure with knowledge that the condition had not occurred; 4. That Plaintiff was harmed; and 5. That Defendant's conduct was a substantial factor in causing Plaintiff's harm. A patient can consent to a medical procedure by words or conduct.





Consent Lawsuit

So you want to spend 2 months in trial?

- Patient = 45 Year-old female physician with former privileges at our ASC
- Contends only consented to surgery with fiberoptic intubation- alleged "conditional consent"
- Writes difficult intubation on Pre-anesthesia Questionnaire
- Pre-op discussions with nurse and anesthesiologist
- Anesthesia consent form makes no mention of fiberoptic intubation
- Nasal-tracheal intubation <u>without</u> use of fiberoptics
- Claims "traumatic" intubation, resulting in hypoxic event
- Claims brain damage, unable to return to work as physician and \$15 million in damages
- Sues anesthesiologist, ASC Medical Director, and ASC for battery and negligence
- Trial involves 31 witnesses, lasts 2 months, with ASC rep and physicians present every day
- Result: Jury verdict for defense, ASC seeks costs \$250k+

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	Lessons Learned
•	 Written consent forms were crucial to defense "No guarantees regarding anesthesia services to be provided" "Conditions may require additional or different anesthetic monitoring or techniques" Others may be provide anesthesia services Disclosure of risks including "brain damage" "I've been given the opportunity to ask questions" and consented to anesthesia and procedure Date and time of patient signature Surgical consent- physicians are independent contractors and agents of patient Get the consent in writing Use "long form" consent – help us to help you
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Physician, Facility & Anesthesia What is the difference between a physician consent, facility consent and anesthesia consent? Do you need separate consents for the procedure and anesthesia? (from a legal standpoint, not accreditation body requirement) Do you need to list risks/benefits/alternatives? Who gives the anesthesia informed consent information to the patient? Can they sign the consent before this given?

Physician, Facility & Anesthesia
 Must give consent prior to agreeing to surgery GI Vascular Facility must ensure that the practitioner responsible for the care obtained consent Should give consent prior to agreeing to administration anesthesia Anesthesia consents should contain: Explanation of the anesthesia, benefits, risks, alternatives, blood and blood product information Who can give anesthesia information? CRNA? MDA? Surgeon? If not the provider, it raises the risk that a non anesthesia provider is not equipped to give information for informed consent
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Physician, Facility & Anesthesia

- Issues to consider for facility consent process
 - If witness is utilized, they are only ensuring the patient is signing
 - Facility consent discussion should be in a private location and before the patient has received any sedation
 - Ask patient to state the procedure to you
 - Ask patient if they have any questions
 - If a patient expresses unanswered questions or concerns, he or she should not sign the form until the physician has addressed all concerns



Informed Consent in Other States (Similar)

TEXAS PHYSICIAN CONSENT

"...for a patient to recover against a provider for lack of informed consent, the patient must show that the provider was negligent in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent."

- §601.2 Procedures Requiring Full Disclosure of Specific Risks and Hazards—List A
- §601.3 Procedures Requiring No Disclosure of Specific Risks and Hazards--List B
- §601.4 Disclosure and Consent Form
- §601.5 Disclosure and Consent Form for Radiation Therapy
- §601.6 History
- §601.7 Informed Consent for Electroconvulsive Therapy
- §601.8 Disclosure and Consent Form for Hysterectomy
- §601.9 Disclosure and Consent Form for Anesthesia and/or Perioperative Pain Management (Analgesia)











Reproductive Consents	
 Sterilization procedures Failed sterilization Complications Spousal consent (Not required) Consent Time Limits Abortions Parental consent of minors 	
 Waiting period Spouse notification 	









Withdrawal of Consent/Refusal of Treatment

- Leaving AMA
 - Develop a policy on AMA
 - Have a form for the patient to sign
 - Document conversations leading up to the withdrawal of consent

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The 2020 Webinar Line Up!							
DATE	G	CE	WEBINAR TOPIC	SPEAKER			
January 27	20 min		ASC Quality Reporting Update	Gina Throneberry			
February 28	60 min	\checkmark	Physical Environment Checklist/How to Talk to an Engineer	John L. Crowder, Jr.			
March 30	20 min		Anesthesia Services	Chris Caldwell			
April 24	60 min	\checkmark	Credentialing Review	Crissy Benze			
May 26	20 min		Medical Record Audit Walkthrough	Debra Stinchcomb			
June 26	60 min	\checkmark	Current Trends in HIPAA and Cybersecurity	Kurt Bratten, Esq.			
July 27	20 min		Customer Service	Vanessa Sindell			
August 28	60 min	\checkmark	Sterile Processing Department Best Practices	Dave Walles			
September 28	20 min		How to Make a Performance Appraisal Effective	Regina Boore			
October 30	60 min	\checkmark	Leadership Panel	TBD			
November 30	20 min		Annual Survey Watch Report	Leanne Gallegos			
December 28	60 min	\checkmark	Problem Employees: How to Manage, How to Win	Abtin Mehdizadegan			

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