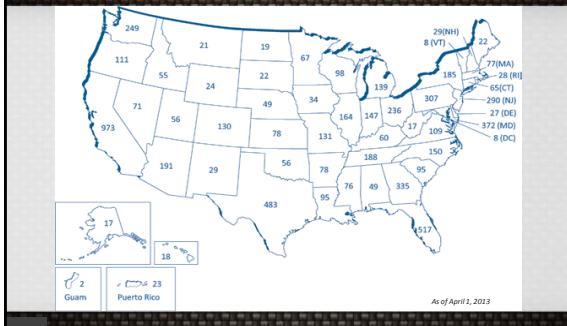


The ASC Market



The Road to a Lawsuit

"The Simplified Version"

1. Establish a duty
2. Breach the duty
3. Cause damages/death
4. Compliant filed & notice served
5. Arbitrate, Settle, Litigate, or Prevail

Common Reasons ASCs are Sued

- Injury in ASC
- Medication Errors
- Anesthesia Errors
- Surgery Errors (Including retained objects)
- Infections & Post-Op Complications
- Improper Consent

Lawsuits & Infections

1. Knee Post-Op Infection

- Soiled bandages not changed
- Post-Op instructions not given
- No follow-up call to patient
- Patient calls not returned by ASC
- Patient presents to ER
- Required hospitalization, IV Ab, Pain Management

Lawsuits & Infections

Cost for failing to follow Infection Control Protocols

\$1.6M

Lawsuits & Infections

2. Spinal Surgery

- Sterilizer recorder out of paper
- No written protocols/policies
- Loads running failed
- Instrumentation used in OR
- Resulted in Hep B & HIV exposure
- Patient requires ongoing testing

Lawsuits & Infections

Cost for failing to follow Infection Control Protocols

\$3.5M

Standards of Care

- The standard of care owed to patients is the level of skill, expertise, and care possessed and practiced by one in the same or similar community, and under similar circumstances.

Where to Find Standards of Care

- State Regulations & Laws
- State Licensing Boards
- Federal Statutes & Laws
- CMS COPs
- Accreditation Standards – TJC/AAAHC
- National Organizations – ASCA, AMA, ANA
- Certifications – APIC, CDC, AORN, WHO

Standards of Care

Patient: "I don't like the way you people are treating me. Like I'm dirty or something."

Me: "I'm sorry, what are you referring to?"

Patient: "Every person that touches me in here immediately washes their hands. I'm not dirty, you know."

Me: "That is standard practice for every patient in the hospital."

Patient: "Yeah right."



Missouri Standards of Care

Rules of Department of Health and Senior Services
 Division 30 – Division of Regulation and Licensure
 Chapter 30 – Ambulatory Surgical Centers

Missouri Department of Health and Senior Services Website
<http://health.mo.gov/safety/asc/relatedlinks.php>



Missouri Standards of Care

Professional Standards of Infection Control in Ambulatory Care Settings:

- APIC
- CDC
- AORN
- DHSS Surveillance

Missouri Department of Health and Senior Services Website
<http://health.mo.gov/safety/asc/relatedlinks.php>



Missouri Standards of Care

Infection Control

"1. There shall be an active multidisciplinary infection control committee responsible for implementing and monitoring the infection control program. The committee shall include, but not be limited to, the infection control officer, a member of the medical staff, registered professional nursing staff, quality improvement staff, and administration.

This program shall include measures for preventing, identifying, and investigating healthcare-associated infections (HAI) and shall establish procedures for: collecting data, conducting root cause analysis, reporting sentinel events, and implementing corrective actions. These measures and procedures shall be applied throughout the ambulatory surgical center, including as part of the employee health program."

*Missouri Department of Health and Senior Services
19 CSR 30-30.020*



Missouri Standards of Care

"3. The infection control committee shall conduct an ongoing review and analysis of HAI data and risk factors.

Priorities and goals related to preventing the acquisition and transmission of potentially infectious agents will be established based on risks identified."

*Missouri Department of Health and Senior Services
19 CSR 30-30.020*



Missouri Standards of Care

"4. Ambulatory surgical centers shall implement written policies and procedures outlining infection control measures for all patient care and support departments. These measures shall include, but are not limited to, an ambulatory surgical center-wide hand hygiene program that complies with the current Centers for Disease Control and Prevention (CDC) Guideline for Hand Hygiene in Health-Care Settings, which is incorporated by reference in this rule. At a minimum, the program shall require every healthcare worker to properly wash or sanitize his or her hands immediately before and immediately after each and every episode of patient care. Procedures shall include, at a minimum, requirements for the facility's infection control program to conduct surveillance of personnel in accordance with section 197.150, RSMo."

*Missouri Department of Health and Senior Services
19 CSR 30-30.020*

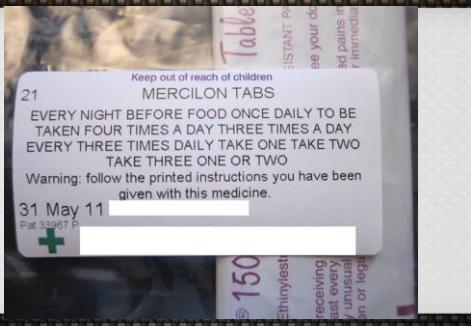


Missouri Standards of Care

"6. There shall be a mechanism for the review and evaluation, on a regular basis, of the quality and effectiveness of infection control throughout the facility."

*Missouri Department of Health and Senior Services
19 CSR 30-30.020*

The Importance of Clear Instructions





Texas Standards of Care

25 TAC §135.11

"(b)(12)(A) Policies and procedures shall be developed following standards, guidelines, and recommendations issued by the Association of periOperative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC)."

TEXAS DEPARTMENT OF STATE HEALTH SERVICES



South Dakota Standards of Care

Infection Prevention and Control

"The facility shall designate an employee to be responsible for the implementation of the infection control program including surveillance and reporting activities. There shall be written procedures that govern the use of aseptic techniques and procedures in all areas of the facility. Each facility shall develop policies and procedures for the handling and storage of potentially hazardous substances (including lab specimens). There shall be a method of control used in relation to the sterilization of supplies and a written policy requiring sterile supplies to be reprocessed. The facility shall provide orientation and continuing education to all personnel on the facility's staff on the cause, effect, transmission, prevention, and elimination of infections. Each facility shall develop a written policy for evaluation and reporting of any employee with a reportable infectious disease."

44:76:02:10 Infection Prevention and Control



Kansas Standards of Care

Ambulatory Surgical Center Regulations

"(a) Each ambulatory surgical center shall establish and maintain an ongoing infection control program. The program shall be based upon guidelines established by the Centers for Disease Control and the licensing department. The program shall include the following:

- (1) Measures for the surveillance, prevention, and control of infections;
- (2) the assignment of the primary responsibility for the program, as well as medical staff participation and review of findings, to an individual;
- (3) written policies and procedures outlining infection control measures and aseptic techniques;
- (4) orientation and ongoing education provided to all personnel on the cause, effect, transmission, and prevention of infections;
- (5) policies and procedures that require all employees to adhere to universal precautions to prevent the spread of blood-borne infectious diseases"

28-34-58a. Infection Control



Arkansas Standards of Care

SECTION 39: AMBULATORY SURGERY CENTERS

"There shall be a comprehensive list of communicable diseases for which patients shall be isolated and for which there are visitation restrictions. The list, and other policies and procedures for isolation, shall conform to the latest edition of the Centers for Disease Control and Prevention, Atlanta, Georgia (CDC) Guidelines.

It shall be the duty of the Administrator or his/her designee to report all infectious or communicable diseases in the facility to the Arkansas Department of Health, Epidemiology, as required by the Rules and Regulations Pertaining to Communicable Disease in Arkansas."

Ark. Code Ann. §§ 20-7-109, 110.



Ohio Standards of Care

Ohio Revised Code - Title 37, Chap 3702

"In the case of an ambulatory surgical facility, the standards shall require the ambulatory surgical facility to maintain an infection control program. The purposes of the program are to minimize infections and communicable diseases and facilitate a functional and sanitary environment consistent with standards of professional practice. To achieve these purposes, ambulatory surgical facility staff managing the program shall create and administer a plan designed to prevent, identify, and manage infections and communicable diseases; ensure that the program is directed by a qualified professional trained in infection control; ensure that the program is an integral part of the ambulatory surgical facility's quality assessment and performance improvement program; and implement in an expeditious manner corrective and preventive measures that result in improvement."

3702.30 Ambulatory Surgical Facilities



Louisiana Standards of Care

Chapter 45 §4509

"A chief executive officer shall be named by the governing body to be responsible for assisting in developing and enforcing policies and procedures established by the center.

Additionally, this officer shall be responsible for assuring that the operation of the center is in conformity with all federal, state, and local laws applicable to the operation of an ambulatory surgical center and to each component thereof."

Louisiana R.S. 40:2131-2143



Georgia Standards of Care

290-5-33-09 Professional Services

"Each center will have effective policies and procedures for handling infection control and for recording complications which occur during or after surgery, which includes a reporting mechanism for patients who develop infections or postoperative complications after discharge."

Preparation Checklist for ASC Initial State Licensure Survey

"Infection Control Plan to include: approval by Governing Body/Medical Staff of Nationally Approved Infection Control Guidelines referenced and used, approval by Governing Body of qualified professional trained in infection control, copies of guidelines used, definitions of surgical infections, surveillance plan, employee health, hazardous waste, sterilization, and disinfection procedures."

CHAPTER 290-5-33 - RULES AND REGULATIONS
FOR AMBULATORY SURGICAL TREATMENT
CENTERS



Tennessee Standards of Care

1200-8-10-04 ADMINISTRATION

"Staff education programs and training sessions shall include life safety, medical equipment, utility systems, infection control and hazardous waste practices.

The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff, and administrative staff develops guidelines and techniques for the prevention, surveillance, control, and reporting of facility infections."

**STANDARDS FOR AMBULATORY SURGICAL
TREATMENT CENTERS - CHAPTER 1200-8-10**



Mississippi Standards of Care

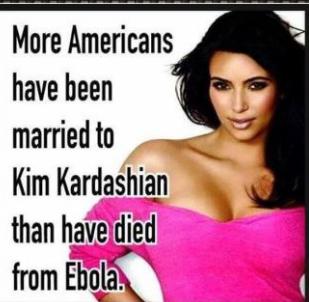
Miss. Code Ann. §41-75-13

Rule 42.18.8 Policies and Procedures [Including Infection Control]

"Written nursing care and administrative policies and procedures shall be developed to provide the nursing staff with acceptable methods of meeting its responsibilities and achieving projected goals through realistic, attainable goals. In planning, decision making, and formulation of policies that affect the operation of nursing service, the nursing care of patients, or the patient's environment, the recommendations of representatives of nursing service shall be considered. Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with Nurse Practice Act of the State of Mississippi and AORN Standards of Practice."

**Title 15: Mississippi State Department of Health
Part 3: Office of Health Protection
Subpart 1: Health Facilities Licensure and Certification**

Infection Control Fact



What is Reasonable Care?

- **Negligence** - A failure to behave with the level of care that someone of **ordinary prudence** would have exercised under the **same circumstance**.
- **Gross Negligence** - Gross negligence is a conscious and **voluntary disregard** of the need to use reasonable care, which is **likely to cause foreseeable grave injury or harm** to persons, property, or both. It is conduct that is extreme when compared with ordinary Negligence, which is a mere failure to exercise reasonable care.

What's the Difference?

- This distinction is important, if gross negligence is found by the trier of fact (judge or jury), it can result in the award of punitive damages on top of general and special damages.

Infection Control Regulations





CMS Regs

§416.51 Condition: Infection Control

§416.51 Condition for Coverage – Infection Control

- The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.



CMS Regs

§416.51 Condition: Infection Control

The ASC's infection control program must:

- Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases;
- Be based on nationally recognized infection control guidelines;
- Be directed by a designated healthcare professional with training in infection control;
- Be integrated into the ASC's QAPI program;



CMS Regs

§416.51 Condition: Infection Control

The ASC's infection control program must:

- Be ongoing;
- Include actions to prevent, identify and manage infections and communicable diseases; and
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.



CMS Regs

§416.51(a) Standard: Sanitary Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.



CMS Regs

§416.51(a) Standard: Sanitary Environment

Policies and procedures for a sanitary and functional environment should address the following:

1. Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;
2. Maintaining safe air handling systems in areas of special ventilation, such as operating rooms;
3. Techniques for food sanitation if employee food storage and eating areas are provided;
4. Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture;
5. Techniques for disposal of regulated and non-regulated waste; and
6. Techniques for pest control.

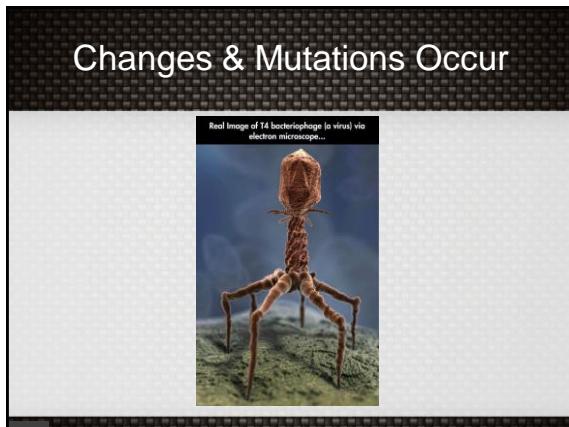
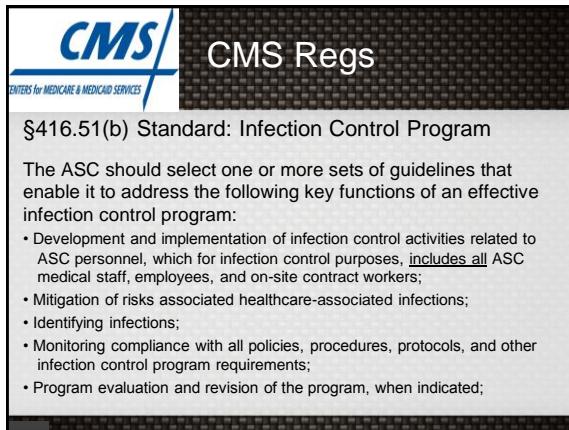


CMS Regs

§416.51(b) Standard: Infection Control Program

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases.

In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.



Determining Damages

The patient will consider all possible losses and harm stemming from the malpractice, including:

- Past and future medical expenses
- Past and future wage losses
- Pain and suffering
- Loss of enjoyment of life (the decreased value of a person's life as a result of the injury, measured by changes in lifestyle, such as the loss of the ability to enjoy sports, walk, or play with children)
- Loss of consortium (losses to family members as a result of the injury, measured by loss of companionship or the loss of the ability to engage in certain activities)

More! More! More!



Nursing Liability

Can Nurses and Infection Control Personnel be held liable when things go wrong?

Nursing Liability

You are responsible for your own conduct



Nursing Liability

- Adverse Effects on your Nursing License

DISCIPLINARY ACTIONS AVAILABLE TO THE BOARD

The Board of Nursing may take disciplinary action against a licensee for violation of the Nursing Practice Act. The Board is authorized to impose any of the following disciplines singularly or in combination: censure, probation, suspension, & revocation.

"(5) Incompetency, gross negligence, or repeated negligence in the performance of the functions or duties of any profession licensed or regulated by chapter 335. For the purposes of this subdivision, "repeated negligence" means the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member of the applicant's or licensee's profession;"

<http://www.moga.mo.gov/mostatutes/stathtml/33500000661.html>



Nursing Liability

- Professional Insurance

You may have a claim against your insurance policy if you hold one. This can result in an increase in future premiums or your ability to obtain future insurance.



Nursing Liability

• Termination of Employment

You may be terminated in some cases for your actions/inactions. Violations of facility policy may justify termination of employment.

In some instances, facilities have a legal obligation to report the employee to their respective State Licensing Board.



Nursing Liability

- Nurse vs Facility

Your interests may be very different from the facility if there is a lawsuit. The facility may NOT be on the same side as you if you are named in the compliant.

You may need representation for yourself in a lawsuit.



Risk Management

How to stay out of court –

- Follow State Regulations
- Work within your scope of practice
- Follow guidelines – CMS, TJC, Etc.
- Follow your policies
- Identify problems to correct
- Ask questions when unsure

Disclaimer

The contents of this presentation are intended to convey general information only and not to provide legal advice or opinions. The contents of this presentation, and the posting and viewing of the information, should not be construed as, and should not be relied upon, for legal advice in any particular circumstance or fact situation. The information presented may not reflect the most current legal developments. Further, it may contain technical inaccuracies or typographical errors. No action should be taken in reliance on the information contained. An attorney should be contacted for advice on specific legal issues. An attorney-client relationship may only be established through direct attorney-to-client communication that is confirmed by the execution of an engagement agreement.

Questions??

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