Accreditation & Regulatory Update
Donald E. Arnold, MD
September 2016

Objectives
• Facility Regulatory and Accreditation Environment
• Selected Regulatory Accreditation Topics
• Resources

“The Survey Team is here …”
Disclosures

• No information from which I might receive financial benefit

• No relevant financial relationships nor commercial interests

• My Perspective

Why the worry?

• Essential for Facilities & Health Systems
  • Medicare & Medicaid Reimbursement - CoP/CIC
  • Commercial Insurance participation
  • State Licensure

• Critical for facility-based physicians
  • Mandatory minimum performance
  • Performance opportunity

Federal Regulations - Facilities

C.M.S

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS
§ 482.52 Condition of Participation: Anesthesia services.

PART 416—AMBULATORY SURGICAL SERVICES
§ 416.42 Condition for Coverage: Surgical services.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS Subpart F: Conditions of Participation: CRITICAL ACCESS HOSPITALS
§ 485.639 Condition of participation: Surgical services

Regulatory Tiers

Accrediting Organization Requirements
“National Guidelines”
Facility & Health System Policies
State Regulation
Federal Regulation

Dynamics of Regulations

Dynamics of Regulations

Anesthesiology Patient Safety Foundation

Joint Commission and Regulatory Fatigue/Weakness/Overabundance/Distraction: Clinical Context Matters
Timothy E. Moore, MD, Joshua W. Soppenfield, MD, Nicholas G. Strouven, MD, and Mark J. Rice, MD
www.anesthesiology.org
August 2015 • Volume 129 • Number 2
Accrediting Organizations

Hospitals/Systems
- TJC
- AAHHS
- AOA/HFAP
- DNV Healthcare

ASC
- TJC
- AAAHC
- AOA/HFAP
- AAAASF

AAAASF

- Lean
- Transparent
- Long Term Focus: Quality & Safety
- Standards:
  - Outcomes
    - Room construction
    - Pulmonary Embolism
    - SSI
    - Medication Safety

AAAHC

- Largest Ambulatory AO
  - 6000+ organizations
- High “customer” satisfaction
  - Links to State Licensing Requirements
  - Clinical Benchmarking Reports
  - Patient Safety Toolkits
  - Responsive Consultative Guidance
- Evolution
**AA:** AAAHC + AAHHS + AOA HFAP

- **DNV**
  - US accreditation since 2008
  - Transparent; Stable Standards
  - Authority: NIAHO integrates ISO 9001
  - **CMS**
  - **NIAHO - ISO 9001**
  - **Hospital's QMS**
  - Application
    - Systematic approach to managing quality
    - Organization defines priorities beyond CoP
    - Focus is now on Continual Improvement

- **TJC**
  - **Large footprint**
    - 21,000 HCOs and programs
    - 1000 surveyors
  - Authority:
    - Accreditation requirements exceed CoP
TJC Hospital/System Accreditation

- Emergency Management
- Environment of Care
- Human Resources
- Infection Prevention and Control
- Information Management
- Leadership
- Life Safety
- Medical Staff
- Medication Management
- National Patient Safety Goals
- Nursing
- Performance Improvement
- Provision of Care
- Record of Care
- Rights and Responsibilities of the Individual
- Treatment, and Services
- Transplant Safety
- Waived Testing

TJC Accreditation - Challenges

- Broadly written standards
  - Contrast to ambulatory AO's
- Lack of Transparency
- Disconnect
  - Standards Development - Office Staff
  - Standards Survey – Survey Staff
- Historical Result
  - Theory meets Reality

TJC Accreditation - Improvements

- Patient Safety Focus
  - Sentinel Event Unit
  - Physician Leadership Forum
  - Center for Transforming Health Care
- Too many Standards
  - Removal of hundreds of EP
  - Organization should develop “policy and process”
- Patient Safety Systems
- REFRESH
TJC Accreditation - REFRESH

REFRESH Projects
- Real-time information gathering between surveyors and Standards Interpretation Group during survey
- Enhanced mobile technology
- Fewer standards
- Revised criticality models
- Easier & less complex decision process
- Streamlined post-survey process
- Higher consistency in interpretation of standards

TJC Accreditation - REFRESH

Lesser Intensity
- To align with CMS’s minimum requirements for an acceptable Plan of Correction

Greatest Intensity
- To align with CMS’s minimum requirements for an acceptable Plan of Correction – PLUS – additional validation of implementation and/or evidence of sustainment

CMS Hospital Conditions of Participation

§482.52 Condition of Participation: Anesthesia Services

§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program
§482.22 Condition of Participation: Medical Staff
§482.25 Condition of Participation: Pharmaceutical Services
§482.42 Condition of Participation: Infection Control
§482.51 Condition of Participation: Surgical Services
CMS ASC Conditions for Coverage

§416.42 Condition for Coverage: Surgical Services
§416.42(a) - Standard: Anesthetic Risk and Evaluation
§416.42(b) - Standard: Administration of Anesthesia
§416.42(c) - Standard: State Exemption

§416.43 Condition for Coverage: Quality Assessment and Performance Improvement
§416.45 Condition for Coverage: Medical Staff
§416.48 Condition for Coverage: Pharmaceutical Services

§416.51 Condition for Coverage: Infection Control

Applicable Regulations

“Follow The Money”

Applicable Regulations - OIG

Ambulatory surgical centers—payment system:
- We will review the appropriateness of Medicare’s methodology for setting ambulatory surgical center (ASC) payment rates under the current payment system. We will also determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. A change in federal law required the Secretary.
Conditions for Coverage

Conditions of Participation

CfC: Practices must conform to acceptable standards of practice for medication administration. "Accepted professional practice" and "acceptable standards of practice"

CoP: The hospital should have a means to incorporate "recommendations from national associations and governmental agencies"

Selected Regulatory Accreditation Topics

- CMS CoP & CfC
  - Supervision
  - Patient Evaluation
- Medication Management
- Infection Control
- QAPI
- Evolving Issues in Practice
- Self-Inflicted Injuries

Supervision

CoP §482.52(a): Organization & Staffing

Supervision

- Define locally

Immediately Available – Immediate Availability

§482.52(a):
- “Physically located within the same area … e.g., in the same operative/procedural suite, or in the same labor and delivery unit, and”
- “Not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.”
Supervision
CfC §416.42(b) - Standard: Administration of Anesthesia

Supervision
• Define locally

Supervision CRNA
• Explicit provision in policy if non-anesthesiologist

Supervision CAA
• §416.42(b) & (c) Immediately Available
• Physically present in the ASC; and Prepared to immediately conduct hands-on intervention if needed.

Immediately Available – Immediate Availability

42 CFR § 415.110
Medicare Claims Processing Manual
• Chapter 12 - Physicians/Nonphysician Practitioners
  • §50 - Payment for Anesthesiology Services

Offers definition for Immediately Available
Recommends development of local policy
Offers considerations
Post-Anesthesia Evaluation

§482.52(b)(3) - A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, no later than 48 hours after surgery or a procedure requiring anesthesia services.

- The evaluation is required any time general, regional, or monitored anesthesia has been administered to the patient.
- Specified elements for the evaluation
- The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area.

§416.42(a)(2) - Standard: Anesthetic Risk and Evaluation

- … must be completed and documented before the patient is discharged from the ASC.

Medication Management - Policy

Develop policy that ensures appropriate:
- Security and Storage
- Labeling
- Administration
- Expiration and Disposal
- Related concerns:
  - Infection Prevention
  - Opioids

Medication Management – Security

Ensure key elements in local policy
- Define how and when OR and Procedural Units are secure
- Scheduled Medications
- Hospital/Facility personnel must be
  - authorized to be in the secure area with meds
  - trained in medication security
  - Medications on top of cart are an area of risk
Medication Management - Labeling

What:
• Any medication “not immediately administered”

When:
• Upon transfer from “original packaging”

How:
• Expiration times/dates required?

Medication Management – Neuraxial

STATEMENT ON STANDARD PRACTICE FOR AVOIDANCE OF MEDICATION ERRORS IN NEURAXIAL ANESTHESIA

American Society of Anesthesiologists

Committee of Origin: Committee on Quality Management and Departmental Administration (QMDA)
(Approved by the ASA House of Delegates on October 20, 2010, and last amended on October 28, 2015)

Statement: Labeling sterile syringes is not required when an anesthesiologist is performing a spinal or epidural anesthetic under sterile conditions without any breaks in the process; the medications are immediately administered and given one of the tests and controls of the anesthesiologist.

Medication Management – Expiration

USP 797

• Immediate-Use CSPs
  First One-Hour Rule
  • Administration begins no later than one hour following the start of preparation
  Second One-Hour Rule
  • If administration has not begun within 1 hour, CSP needs to be discarded promptly, properly and safely
• Single-Use Containers
  Third One-Hour Rule
  • Opened or needle punctured containers shall be used within 1 hour, then discarded
  • Bags, bottles, syringes, vials
  • Opened ampoules shall not be stored for ANY period of time
Medication Management – Expiration
USP 797

APIC position paper: Safe injection, infusion, and medication vial practices in health care

Laura A. Bell, MPH, MS, DO; Jasmine Neufeldt, RN, MSN, CRNI; Terri Young, RN, MSN, CRNI; Kristy B. Cox, RN, CRNI; et al.

Medication Management – Expiration
USP 797

Department of Health and Human Services
Centers for Medicare & Medicaid Services (CMS)

Sentinel Event

If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient to allow for safe and accurate titration of dosage, use a new needle and new syringes for each entry.21 Note: USP 797 states that single-dose/single-use vials opened in less than ISO Class 5 air quality

Mercy

9/6/16
Medication Management – Expiration
USP 797

Draft Provisions:
Reconstituting/Diluting in accordance with manufacturer’s label is not compounding
Administration in accordance with CDC/manufacturer’s label

ASA Ask:
 Provision for reconstituting/diluting for anticipated emergency procedures

Medication Management – Multi-Dose Vials – CDC & ASHSP

Key Requirements:
• Date and discard within 28 days, unless otherwise specified by manufacturer label
• Dedicated to a single patient as much as possible
  • If MDVs are used for more than one patient, they must not enter the immediate treatment area
  • Spiking device should never be left inserted into a medication vial septum for multiple uses

• Challenges:
  • Bedside barcode scanning
  • Anesthesia Carts
Malignant Hyperthermia in the Ambulatory Surgery Center  

**How Should We Prepare?**  


---

**Medication Management**  
**MH & Succinylcholine**

- TJC  
- AAAASF  
  
  500.23 Malignant Hyperthermia: This section applies if potential MH triggering agents such as the potent inhalation anesthetics .... are ever used or are present in the facility.

- AAAHC  
  
  Any triggering agents = MHAUS protocols

---

**Medication Management**  
**MH & Succinylcholine**

- [Condition of Participation: Surgical Services](#)  
  
  Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical care.

- [Standard for Coverage: Environment](#)  
  
  An ASC must coordinate its care with the ASC's patient population. Appropriate for the ASC's patient population.

- [Anesthesia](#)  
  
  Appropriate for the ASC's patient population. A risk procedure. For example, if an ASC uses anesthetic agents that carry a risk for malignant hyperthermia, then the ASC's provider must ensure that the agents are properly identified and stored in an emergency condition. The amount of medications that must be immediately available to the ASC must be based on the specific factors such as malignant hyperthermia emergency, as well as ASC patient characteristics. Costs for the ASC's use of Malignant Hyperthermia Assisted Emergency: An ASC that performs invasive procedures on obese patients would need to have more emergency medications available than would an ASC that specializes in plastic procedures.
Infection Control – CMS

§416.51 Condition for Coverage – Infection control

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

§482.42 Condition of Participation: Infection Control

• The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
Endotracheal Tubes

• ETTs stored in closed packages until use

• No current evidence against “pre-opening ETT”
  • organization may evaluate risk/benefit, formulate a policy based on a consistent process

• Document and follow policy

Laryngoscopes

• Laryngoscopes are semi-critical devices, all of which require high level disinfection or sterilization

• Blades
  • Should be packaged individually – peel pack or plastic bag
  • May be partially removed for testing before use

• Laryngoscope handles require decontamination
  • Manufacturers “Indications for Use” recommendations

AORN Guideline for Surgical Attire

Background

Authority

Current State
§482.42 Condition of Participation: Infection Control

- Conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies.
- Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines include:
  - Centers for Disease Control and Prevention (CDC)
  - Association for Professionals in Infection Control and Epidemiology (APIC)
  - Society for Healthcare Epidemiology of America (SHEA)
  - Association of periOperative Registered Nurses (AORN)
  - The U.S. Occupational Health and Safety Administration (OSHA)
The ACS guidelines for appropriate use are based on professionalism, common sense, decency, and the available evidence. They are as follows:

ASA - AORN

- Dialogue
- Additional review
- Developing recommendations:
  - Engage locally in Policy development
    - Scope, goals, objectives
  - Resources
    - Regulatory requirements
    - Additional broadly sourced materials
    - Support compliance with local policy

QAPI

§416.43 Condition for Coverage: Quality Assessment and Performance Improvement

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services, involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.
CMS Policy & Payment

QAPI – Provider Payment

Hospital Value-Based Purchasing (VBP) Program
Hospital Readmissions Reduction Program
Hospital Acquired Condition (HAC) Reduction Program

QAPI: Quality Improvement Program for Healthcare Providers
MIPS: Medicare Access and CHIP Reauthorization Act
APM: Advanced Alternative Payment Models

DataWatch: US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures

FFY 2015 Value-Based Purchasing

21
### CMS Policy & Payment

#### Ambulatory Surgical Center Measure Reporting Start Dates

<table>
<thead>
<tr>
<th>Measure</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACO-1</td>
<td>1/1/2023</td>
</tr>
<tr>
<td>ACO-2</td>
<td>1/1/2024</td>
</tr>
<tr>
<td>ACO-3</td>
<td>1/1/2025</td>
</tr>
<tr>
<td>ACO-4</td>
<td>1/1/2026</td>
</tr>
</tbody>
</table>

#### CMS.gov

- **Centers for Medicare & Medicaid Services**
- **Audit, Evaluation, and Reporting**
- **Public Comment**

#### Project Title: Development of Facility-Level Quality Measures for Unplanned Hospital Visits after Selected Ambulatory Surgical Center Procedures

**Timeline:**
- Start Date: January 1, 2023
- End Date: December 31, 2026

#### Quality & Safety >>> Public Reporting

**Anaesthesia Quality and Safety**

- **Regulatory Mandates**
- **Health reform**
- **Includes Financial Mandates**
- **Integrated Technology**
- **Data analysis and reporting**
- **Human factors**
- **Process improvement**
- **Lean – Six Sigma**
Evolving Issues - Concurrent Procedures

II. RELATION OF THE SURGEON TO THE PATIENT

A. Informed Consent
D. The Operation – Intraoperative responsibility of the primary surgeon

General Statement
Concurrent or Simultaneous Operations
Overlapping Operations
Multidisciplinary Operations
Delegation to Qualified Practitioners
Procedure-Related Tasks
Unanticipated Circumstances
Surgeon-Patient Communication (Section II.A.)
Definitions

Evolving Issues - System Consolidation

Mergers & Acquisition
- Facility & Hospital consolidations
  - ASC
  - Across AO
  - CAH
- Systems crossing state lines

Need to Assess
- Applicable Regulatory authority
- AO
- Policies

System Consolidation - Example

Mergers & Acquisition

Large Academic-Private Health System
acquires 2 OR ASC – Hand surgery
- Well deserved reputation
- Highly productive
- Single anesthesiologist

ASC converted to HOD – Hospital AO/Policies applicable
- Impact on PreOP/Postop care
- Impact on mode of anesthesia practice
Evolving Facility and Health Systems

Need for System Policy templates
System-wide vs. Locally adapted

Avoid Self-Inflicted Injuries

Two most common QRA inquiries:
OR Attire
Hand Hygiene

Avoid Self-Inflicted Injuries – Attire Policy

Example:
…… an anesthesia staff member was observed to exit OR 3 and enter OR 4 wearing the same face mask. Upon leaving OR 4 and prior to entering OR 5 the staff member in responding to a phone call loosened the face mask and upon concluding the call re-applied the mask and re-entered OR 5.
Avoid Self-Inflicted Injuries
Infection Prevention Policy

Example:
Surveyor #3 observed the hand hygiene practices of Anesthesia Staff #21 caring for Patient #7. Between 2:30pm and 3:15pm while delivering medications and fluids the Staff Member failed to perform hand hygiene before and after administration of each medication.

Avoid Self-Inflicted Injuries
Accreditation Organization Staff

Prepare:
Crosswalk Conditions/State Req – AO – Local Policy
Facility Accreditation & Regulatory Staff

Engage:
Local policy development – avoid overreach
Understand local compliance requirements
Resources

- Facility Accreditation Staff
- Accrediting Organizations
- ASA

Resources: Facility Accreditation Staff

- Prospective and continuous engagement
- Regulatory and accreditation concerns
  - System-based experience
  - AO Guidance
- Access AO Tools

Resources: Facility Accreditation Staff

Connect®

The Joint Commission

Connect®

The Joint Commission Connect

- Connectivity
- Communication
- Resources and Loy
- Connect

Contact

- Customer Service
- Customer Help
- Customer Information

Useful Tools

- Connect Knowledge Center®
- Customer Service
- Connect Knowledge Center®
- Customer Service
- Connect Knowledge Center®
- Customer Service
- Connect Knowledge Center®
- Customer Service
- Connect Knowledge Center®
- Customer Service
- Connect Knowledge Center®
ASA Resources

- ASA Committees
  - QMDA
  - CASC
  - CoPM
- ASA Staff
  - Education Department
  - Quality & Regulatory Affairs
  - Payment & Practice Management

Quality & Regulatory Affairs

Staff Contacts

- Matt Popovich, Ph.D
  ASA Director of Quality and Regulatory Affairs
- Beth Quill, J.D.
  ASA Quality and Regulatory Affairs Specialist
- ASA Quality and Regulatory Affairs
  qra@asahq.org
  (202) 289-2222

Contact me!

don.arnold@mercy.net

Thank You!