IMPLEMENTATION OF CMS INTERPRETIVE GUIDELINES: BEST PRACTICES

Norman A. Cohen, M.D.
ASA Vice President for Professional Affairs
Associate Professor of Anesthesiology & Perioperative Medicine
Oregon Health & Science University
Portland, Oregon

Disclosures | None

Joint Commission Store

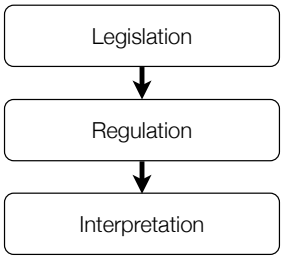
So for $599, you can learn about the rules governing CMS surveys, provided by a deemed accreditation organization.

Or you can listen to me…

Objectives

- Describe the legislative and regulatory basis for hospital compliance with the Medicare Conditions of Participation (COP)
- Differentiate between the COP and Interpretive Guidelines (IG)
- Cite the agencies and organizations that may survey a hospital for compliance with Medicare regulations
- Delineate the requirements for anesthesia services in hospitals, including provider requirements and quality review
- Report the key recent revisions to the COP
- Summarize the obligations of directors of anesthesia services in implementing the COP and IG

Legislation, Regulation & Interpretation - Overview



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Legislation - Social Security Act

- Congress *amended* the Social Security Act in 1965
  - Created Medicare Part A (hospitals) and Part B (physician and other supplementary services)
  - Different funding mechanisms
- Later amendments created Medicare managed care (Part C *BBA 1997*) and the prescription drug benefit (Part D *MMA 2003*)
- Part E includes miscellaneous provisions including key definitions
  - *Sec. 1861. [42 U.S.C. 1395x] paragraph e* defines ***Hospital***

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Congressional Requirements of *Hospitals*

- Deliver therapeutic and diagnostic services
  - Medical diagnosis, treatment and care
  - To injured, sick and disabled individuals
  - Under physician supervision
- Maintain clinical records
- Medical staff governed by bylaws
- 24 hour nursing services
- Utilization review
- State licensure, if required
- ***AND…***

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Carte blanche

- The Secretary of HHS was given wide latitude in broadening the requirements for hospitals through ***regulation***
  - [A hospital] "*meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.*"

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Regulation - Hospital Conditions of Participation (COP)

- Regulations put flesh on the skeleton of legislation
- Conditions of Participation are *regulations*
  - Promulgated by the Department of Health & Human Services
  - Implements Medicare Part A provisions of the Social Security Act
- Regulations have the force of law, same as legislation
- Procedural requirements found in the *Administrative Procedures Act (APA)*

Administrative Procedures Act

- Publication of proposed rule making in *Federal Register*
  - Notice of Proposed Rule-making (NPRM)
- Comment period of varying durations
- Response to comments in Final Rule
  - Additional comment period in some cases
    - Typically if changes take place between proposed and final rule

Interpretation - Interpretive Guidelines (IG) to the COP

- Regulatory characteristics
  - Very detailed
  - Complex
  - Often open to interpretation
- Interpretive Guidelines
  - Regulatory agencies explanation and clarification of regulatory law
  - Applicability in specific circumstances and compliance requirements

Interpretive Guidelines – Standing as Law

- Considered *interpretive rules*
  - Lower force than regulation or legislation
    - Formal rule-making requirements of *APA* do not apply
  - Comment period not required, but may occur at discretion of agency
  - Can not create a new legal standard
  - Not published in *Federal Register*
  - Usually available on agency web site or from Government Printing Office

Limits of Discussion

- HHS/CMS have published formal rules and interpretive guidelines for
  - Hospitals
  - Ambulatory Surgery Centers
  - Critical Access Hospitals
  - Others
- Will focus on COP and IG for hospitals as apply to anesthesia services

Surveying for Compliance | Medicare requirements

HHS & CMS Responsibilities

- Must assure the integrity of the Medicare program
  - Medicare beneficiaries should receive the care promised under law
  - Surveying for compliance is part of this process
  - Delegation per federal law
    - State surveying agencies (SA)
    - Deemed Accreditation Organizations (AO)

State Surveying Agencies

- Default surveying organization
- Surveys conducted consistent with Medicare's State Operations Manual (SOM)
  - SOM includes COP and IG
  - Specific surveying elements delineated
    - Demonstrates compliance with COP/IG
  - SOM available online at cms.gov Web site

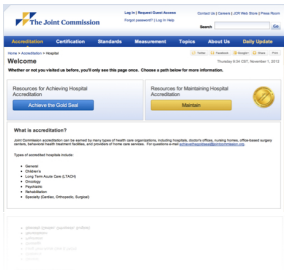
Accreditation Organizations (AO)

- Deemed by HHS/CMS to assure compliance with
  - Legislation, regulation, interpretive guidance
  - Surveying requirements must meet, at minimum, SOM requirements
  - Voluntary process with cost to facility
  - SA surveys typically only occur in small subset for “validation”
    - Non-compliance on validation leads to continued oversight by SA
    - Otherwise AO has oversight responsibility

Deemed AO

- List found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-08.pdf
  - The Joint Commission (TJC)
    - Had special status until Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) passed
    - Now one of several deemed organizations beginning in 2010
  - Det Norske Veritas (DNV)
    - Integrate COP with ISO 9001(Standard for the formation and implementation of the Quality Management System)

http://dnvaccreditation.com



http://www.jointcommission.org/

Accreditation Organizations

Audience Response:

Who performs your Medicare hospital surveys?

1.TJC
2.DNV
3.My state
4.Other

COP, IG and Anesthesia | Anesthesia specific requirements

Anesthesia's Special Place

- Anesthesia historically considered a "high risk" part of care
- The Conditions of Participation *regulations* have specific requirements related to anesthesia care
- The COP define requirements for anesthesia services:
  - Organization and staffing
  - Delivery of services
  - State exemptions related to state CRNA supervision "opt-out"

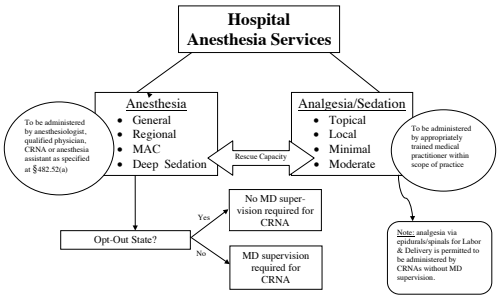
Organization & Staffing

§482.52 Condition of Participation: Anesthesia Services

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

Interpretive Guidelines & State Operations Manual

- Provide expanded detail on
  - Organizational requirements
  - Pre-, intra-, and post-anesthesia care
  - Opt-out
- Surveying criteria for SAs, also applicable to AOs



Other Considerations

- Other aspects of COP/IG/surveying also apply to anesthesia delivery
  - Surgery
  - Pharmacy
  - Laboratory
  - Imaging
  - Transfusion services
- Medical staff organization
- Hospital wide Quality Assessment and Performance Improvement (QAPI) requirements

Recent revisions | COP and IG

Revisions

- CMS published a number of revisions to COP in May, 2012
- CMS revised IG in both 2010 and 2011
- Will cover IG revisions then COP revisions, following CMS timeline for change

Interpretive Guideline Revisions

- All anesthesia a single service
- Qualifications for director of anesthesia
- Anesthesia service responsibilities include both analgesia and anesthesia
- Differentiating and classification of anesthesia and analgesia
- Qualification and supervision requirements
- Moderate sedation clarifications
- Clarifications regarding timing and allowed locations of various required anesthesia activities as well as handling exceptional circumstances

Single Service

- All anesthesia services must be under the direction of a single physician
  - MD or DO
  - Being an anesthesiologist is NOT a prerequisite for this position

Director Qualifications

- Governing body of hospital (typically a Board of Directors) determines qualifications for director of anesthesia services
  - Medical staff provides recommendations
  - Both an opportunity and a threat for anesthesiologists

Analgesia and Anesthesia

- For purposes of accreditation, define anesthesia to include topical and local anesthesia, anxiolysis, light, moderate, deep sedation, MAC, general anesthesia, major and neuraxial nerve blocks
- General, regional, MAC/deep sedation are classified as anesthesia
- All others are classified as analgesia

Differentiating & Classifying Anesthesia and Analgesia

- Anesthesia requires physician supervision of nurse anesthetists (states without opt-out)
- Analgesia does not require physician supervision of anesthetists - *labor analgesia*
- Governing body must define location specific policies classifying whether anesthesia or analgesia is provided
  - Consider “nationally recognized guidelines” in this determination

Qualification and Supervision Requirements

- Hospital policies must define qualification and supervision requirements for anesthesia and analgesia
  - By provider category
  - By anesthesia/analgesia category
  - Moderate sedation called out specifically
- Hospital quality program must address both anesthesia and analgesia care

Moderate Sedation Clarifications

- Moderate sedation is ***NOT*** an anesthetic
- Pre-anesthetic evaluation and post-anesthesia visit requirements do not apply to moderate sedation services
  - Note that moderate sedation services do require specified pre-, intra-, and post-activities, but these are not clearly delineated in the COP/IG
  - At a minimum, would recommend reviewing moderate sedation CPT codes and relevant guidance in crafting moderate sedation evaluation and documentation requirements

Clarifications on Timing and Content of Pre-anesthesia Evaluation

- Pre-anesthesia evaluation
  - Between 30 days and 48 hours prior, may perform risk discussion, identification of potential anesthesia problems, perform required testing or consultation, develop anesthesia plan
  - 48 hours to anesthesia start, must update any previously acquired information or plans, review medical history (prescribed medications, allergies, anesthesia history), perform patient interview (as possible based on patient condition), focused physical examination
  - Documentation must be updated and complete prior to anesthesia start

Clarifications on Timing, Allowed Locations & Exceptional Circumstances For Post-Anesthesia Care

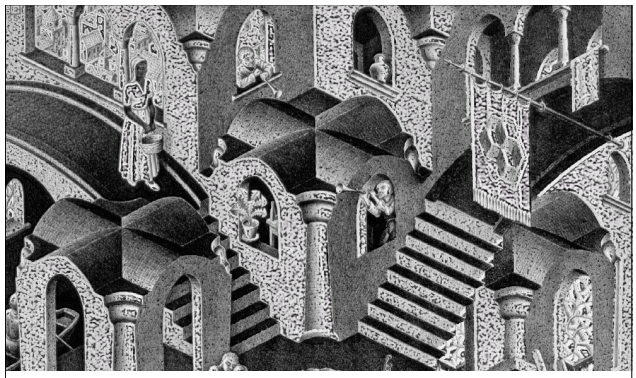
- May assess patient in PACU under certain circumstances
  - Requires sufficient recovery from anesthetic to participate in assessment
  - Must occur before 48 hours of end of anesthetic
  - For patients unable to participate (e.g., critically ill, ventilated), must document both overall status and patient's inability to participate
  - For long-acting blocks extending beyond 48 hours, must document that block not expected to resolve within 48 hours, and document other post-anesthesia elements

Conditions of Participation Revisions

- Published May 2012
- Based on Executive Order in 2011 for regulatory revision addressing burdensome/costly rules

COP Changes Impacting Anesthesia

- Medical staff governance for multi-hospital systems
- Medical staff expansion to include non-physicians c/w state law
- Patient administration of own meds in hospital or critical access hospital
- Reduced regulations for transfusion and medication administration
- Broadened prescriptive authority for non-physicians
- Flexibility for standard order sets
- No longer mandates authentication of verbal orders within 48 hours (state law applies)



Implementation | Suggestions and strategies

Scope

- COP and IG related to anesthesia services
- Not Part B professional billing rules, teaching rules (surgical or anesthesia), medical direction
- Limited to hospital COP/IG but not ASC, critical access hospital or other settings

Implementation Topics

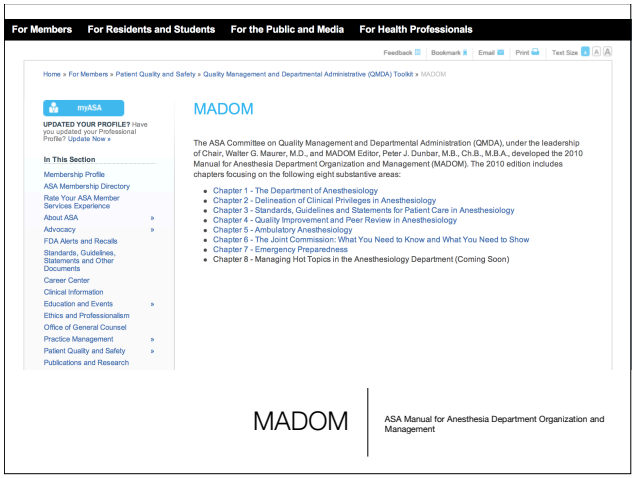
- Director of anesthesia
- Single anesthesia service
- Rescue capacity
- Anesthesia vs analgesia and privileging
- Quality improvement
- Service delivery
- Pre-, intra- and post-anesthesia requirements
- Immediate availability
- Informed consent

Director of anesthesia

- Hospital policies ***must***
  - Define qualifications and responsibilities for this position
    - Physician (M.D. or D.O.)
    - Medical staff input on selection
    - Could require other elements
      - Specialty (anesthesiology)
      - Board certification
      - Minimum experience

Director of anesthesia

- Minimum responsibilities
  - Planning, directing, and supervising all activities of the service
  - Evaluating the quality and appropriateness of the anesthesia services provided to patients as part of the hospital's Quality Assessment/ Performance Improvement (QAPI) program
- Other
  - Consistent with state law
  - May consider guidance from professional organizations



SOM survey requirements – director

- Request a copy of the organizational chart for anesthesia services
- Determine that a doctor of medicine or osteopathy has the authority and responsibility for directing all anesthesia services throughout the hospital
- Look for evidence in the director's file of the director's appointment privileges and qualifications, consistent with the criteria adopted by the hospital's governing body. Review the position description. Confirm that the director's responsibilities include at least the following:
  - Planning, directing, and supervising all activities of the service
  - Evaluating the quality and appropriateness of the anesthesia services provided to patients as part of the hospital's QAPI program

Single anesthesia service

- Single well-organized service under the direction of a single physician
- Applied in all settings where analgesia and anesthesia provided
- CMS encourages but does not require that policies be developed collaboratively with other stakeholders
  - E.g., surgery, pharmacy, nursing, safety experts

Rescue capacity

- No "clear boundary" between levels of sedation on the sedation continuum
- Those granted privileges for any given level of sedation must have the skills necessary to rescue from the next deeper level of sedation
  - Director of anesthesia must assure policies present, enforced addressing
    - Provider skills (airway management, ACLS, BLS)
    - Management of physiological changes seen with sedation and during rescue
- See also Patient's Rights requirements (COP §482.13(c)(2))

Anesthesia, analgesia and privileging

- The COP specifically define who can provide anesthesia:
  - Qualified anesthesiologist
  - Other physician (MD/DO)
  - Dentist, podiatrist, oral surgeon when permitted by state law
  - CRNA
  - Anesthesiologist Assistant under the direction of an anesthesiologist

Non-anesthesiologists

- Interpretive guidelines require hospital policies to define:
  - Circumstances under which other MD/DO provide anesthesia services
  - Criteria for podiatrists, dentists and oral surgeons c/w state law
- Deep sedation is an anesthesia service (inclusive within MAC)
  - Intensivists, emergency physicians, others may request privileges and policies must address experience requirements & limitations

SOM survey requirements–single service & privileging

- Request a copy of and review the hospital's anesthesia services policies and procedures
  - Do they apply in all hospital locations where anesthesia services are provided?
  - Do they indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia?
  - Do they address what clinical applications are considered to involve analgesia, in particular moderate sedation, rather than anesthesia, based on identifiable national guidelines? What are the national guidelines that they are following and how is that documented?

Quality improvement

- CMS expects that ongoing quality improvement will lead to periodic review and updating of anesthesia & analgesia policies
  - Adverse event monitoring
  - Medication errors
  - Other quality metrics
- Anesthesia service fully integrated into quality program
  - Quality Assessment/Performance Improvement (QAPI)

SOM survey requirements

- Does the hospital have a system by which adverse events related to the administration of anesthesia and analgesia, including moderate sedation, are tracked and acted upon?

Service delivery

- Anesthesia department policies must address:
  - Consent
  - Infection control
  - Safety in anesthetizing locations
  - Emergency response
  - Reporting and documentation requirements
- Ongoing testing and maintenance requirements
- Staff responsibilities for pre- and post-anesthesia care

Pre-, intra-, and post-anesthesia requirements

- COP sections §482.52(b) (1)-(3)
  - Specify requirements for pre-, intra- and post-anesthesia care
    - Time constraints
    - Qualified providers
    - Specific elements

Pre-anesthesia

- Evaluation performed by a qualified anesthesia provider
- Completed within 48 hours of administration of first drug to induce anesthesia

Pre-anesthesia required elements

- Medical history including prior anesthesia
- Prescription medications and allergies
- Face-face interview and examination
- Anesthesia risk assessment (ASA physical status)
- Identify potential anesthesia problems (airway, IV access, etc.)
- Additional evaluation necessary or review such evaluations
- Anesthesia plan

SOM survey requirements – pre-anesthesia

- Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia
- Determine whether each patient had a pre-anesthesia evaluation by a practitioner qualified to administer anesthesia
- Determine whether each patient's pre-anesthesia evaluation included at least the elements described [on previous slide]
- Determine that the pre-anesthesia evaluation was performed within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for the surgery or a procedure requiring anesthesia services

Intra-anesthesia

- Required elements include
  - Patient name and ID
  - All anesthesia practitioners involved
  - Drugs, routes and dosages
  - Anesthetic technique, positioning, IV and airway devices employed
  - Time-based IV fluids and blood products
  - Time-based vitals, oxygenation, and ventilation
  - Any complications, adverse reactions or complications including response to treatment

SOM survey requirements – intra-anesthesia

- Review records to determine that each patient has an intraoperative anesthesia record that includes the elements described [on prior slide]

Post-anesthesia

- Performed by a qualified anesthesia provider
- Within 48 hours of movement to post-anesthesia care for general, regional or MAC
- Patient must be sufficiently recovered to participate (or exceptions documented)

Post-anesthesia required elements

- Respiratory function
- Cardiac function
- Mental status
- Temperature
- Pain
- Nausea/vomiting
- Post-operative hydration
- Other procedure dependent assessments

SOM survey requirements – post-anesthesia

- Review a sample of medical records for patients who had surgery or a procedure requiring general, regional or monitored anesthesia to determine whether a post anesthesia evaluation was written for each patient
- Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia
- Determine whether the evaluation was performed within 48 hours after the surgery or procedure
- Determine whether the appropriate elements of a post anesthesia evaluation are documented in the medical record

Audience Response:

Does your department track compliance with post-op visits?

1.Yes
2.No

Immediate availability

- Interpretive guidelines definition:
  - *An anesthesiologist is considered immediately available when needed by a CRNA under the anesthesiologist's supervision only if he/she is physically located within the same area as the CRNA, 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.*

Immediate availability considerations

- *"e.g., in the same operative/ procedural suite, or in the same labor and delivery unit"* are examples
- Local policies should explicitly define this term based on patient condition, physical layout, practitioner experience
- Time based responses may be used but are not required
- May defer to independent medical judgment of supervising physician in policy
- Consider inclusion in QAPI program

Immediate availability – ASA definition

- *A medically directing anesthesiologist is immediately available if s/he is in physical proximity that allows the anesthesiologist to return to re-establish direct contact with the patient to meet medical needs and address any urgent or emergent clinical problems. These responsibilities may also be met through coordination among anesthesiologists of the same group or department.*
- *Differences in the design and size of various facilities and demands of the particular surgical procedures make it impossible to define a specific time or distance for physical proximity.*
  - Approved by ASA House of Delegates October 2012
    - https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

Audience Response:

Does your department have a policy defining "immediately available"?

1.Yes
2.No

Informed consent

- COP for surgery addresses informed consent (§482.51(b)(2))
  - *It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.*
- SOM has guidance on crafting a well-designed informed consent in §482.51(b)(2)
- Certain services related to anesthesia care (lines, blocks, TEE, etc.) are surgical procedures and subject to surgical consent requirements

Closing thoughts

- Academic anesthesiology chairs often serve as hospital directors of anesthesia
- Continued Medicare participation depends on meeting the COP or the extended requirements of AOs
  - Failure is costly – both to the institution and to the responsible party(ies)
- Familiarity with Medicare requirements is essential for directors of anesthesia services
- Refer to the latest primary source material from CMS and any designated AO as one prepares for an accreditation visit
  - AO requirements must meet or exceed CMS requirements covered today