AHC Media

Ensuring Compliance with CMS Anesthesia Standards

Monday, June 29th, 2015

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Speaker

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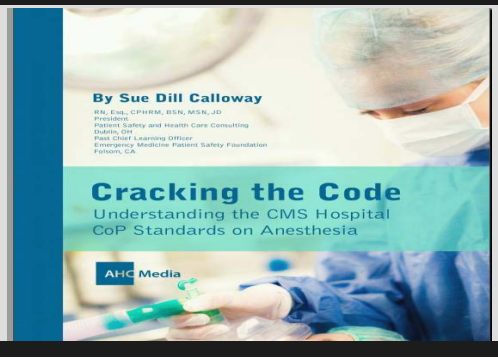
- 614 791-1468 (Call with questions, No emails)
- sdill1@columbus.rr.com

Objectives

- List the areas within the CMS Anesthesia standards that are getting the most citations.
- Describe the policies and procedures CMS requires for anesthesia services.
- Summarize the documentation requirements of the CMS Anesthesia standards.
- Explain the requirements for pre- and post-anesthesia assessments including time-frames.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Author of Book on the CMS Anesthesia Standards



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You Don't Want to Receive One of These

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The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Many revisions since then
  - First regulations are published in the Federal Register then CMS publishes the Interpretive Guidelines and some have survey procedures [2]
  - Hospitals should check this website once a month for changes

[1]www.gpoaccess.gov/fr/index.html [2]www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

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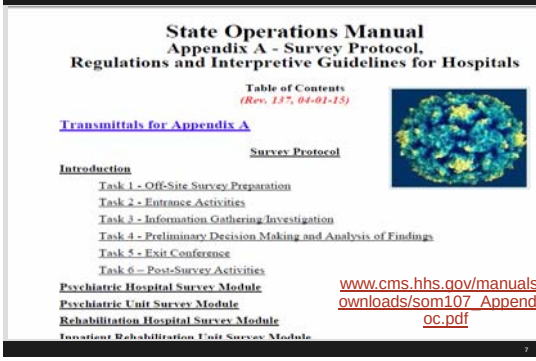
CMS CoP Manual Called SOM



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

Table of Contents
(Rev. 137, 04-01-15)

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

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

CMS Survey and Certification Website

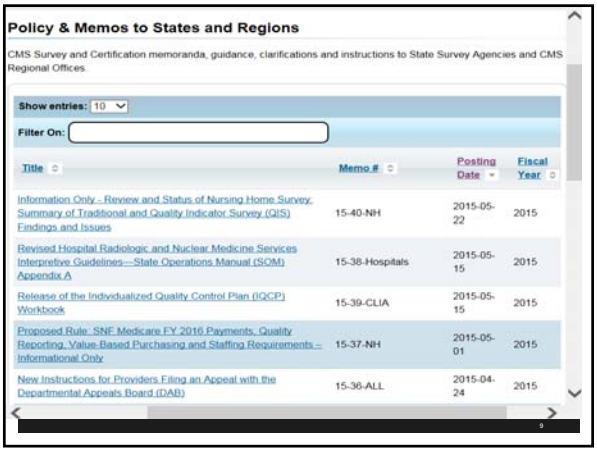
CMS.gov
Centers for Medicare & Medicaid Services

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:

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage



Policy & Memos to States and Regions

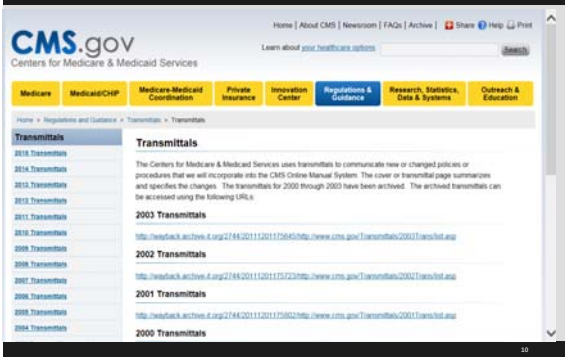
CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Information Only - Review and Status of Nursing Home Survey, Summary of Traditional and Quality Indicator Survey (QIS) Findings and Issues	15-40-NH	2015-05-22	2015
Revised Hospital Radiologic and Nuclear Medicine Services Interpretive Guidelines---State Operations Manual (SOM) Appendix A	15-38-Hospitals	2015-05-15	2015
Release of the Individualized Quality Control Plan (IQCP) Workbook	15-39-CLIA	2015-05-15	2015
Proposed Rule: SNF Medicare FY 2016 Payments, Quality Reporting, Value-Based Purchasing and Staffing Requirements – Informational Only	15-37-NH	2015-05-01	2015
New Instructions for Providers Filing an Appeal with the Departmental Appeals Board (DAB)	15-36-ALL	2015-04-24	2015

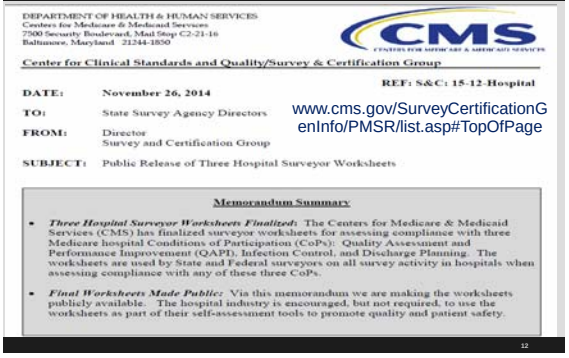
CMS Transmittals



CMS Hospital Worksheets History

- First, October 14, 2011 CMS issues a 137 page memo in the survey and certification section and it was pilot tested in hospitals in 11 states
  - Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey
- Addresses discharge planning, **infection control,** and QAPI (performance improvement)
  - May 18, 2012 CMS published a second revised edition and pilot tested each of the 3 in every state over summer 2012
  - November 9, 2012 CMS issued the third revised worksheet and revised discharge planning one March 2014
  - Final ones issued November 26, 2014

Final 3 Worksheets QAPI



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

DATE: November 26, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Public Release of Three Hospital Surveyor Worksheets

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Memorandum Summary

- ***Three Hospital Surveyor Worksheets Finalized:*** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.
- ***Final Worksheets Made Public:*** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

CMS Hospital Worksheets

- And of course completing the forms helps the hospital to comply with those three CoPs
- Citation instructions are provided on each of the worksheets
- The surveyors will follow standard procedures when non-compliance is identified in hospitals
- This includes documentation on the Form CMS 2567
- Not used in CAH but good tool for CAH to use
- Questions to: **hospitalscg@cms.hhs.gov**

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CMS Hospital Worksheets

- The regulations are the basis for any deficiencies that may be cited and not the worksheet per se
  - IC includes section on **safe injection practices**
- The worksheets are designed to assist the surveyors and the hospital staff to identify when they are in compliance
  - Will not affect critical access hospitals (CAHs) but CAH would want to look over the one on PI and especially infection control
  - Questions or concerns should be addressed to PFP.SCG@cms.hhs.gov or hospitalscg@cms.hhs.gov

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CMS Hospital Worksheets

- However, some of the questions asked might not be apparent from a reading of the CoPs
  - A worksheet is a good communication device
  - It will help clearly communicate to hospitals what is going to be asked in these 3 important areas
  - Anesthesia can **not** give **single dose medications** to more than one person unless prepared in pharmacy
  - Has a section on **safe injection practices** which is very important and all staff should be aware
  - Hospitals should consider attaching the documentation and P&P to the worksheet

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Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

Elements to be assessed		Manner of Assessment Code (check all that apply) & Surveyor Notes		Manner of Assessment Code (check all that apply) & Surveyor Notes
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:				
2. B.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. B.2 Needles are used for only one patient.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ○ No ○ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Interview = 1 Observation = 2 Infection Control Document Review = 3 Medical Record Review = 4 Other Document Review = 5

11.00 x 8.50 in

Page 11 of 42

Injection Practices & Sharps Safety 2 B

- Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids
- Is rubber septum disinfected with alcohol **before** piercing?
- Are single dose vials, IV bags, IV tubing and connectors used on only one patient?
- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
- Make sure expiration date is clear as per P&P
- If multidose vial found in patient care area must be used on only one patient

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Safe Injection Practices Patient Safety Brief

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

www.empsf.org

Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention

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Injection Practices & Sharps Safety

- Are all sharps disposed of in resistant sharps container?
- Are sharp containers replaced when fill line is reached?
  - Are sharps disposed of in accordance with state medical waste rules
  - Hospitals should have a system in place where someone has the responsibility to check these and ensure they are replaced when they are full

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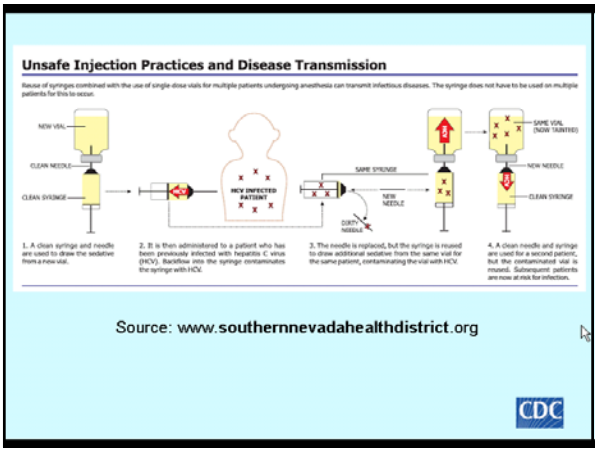

Not All Vials Are Created Equal

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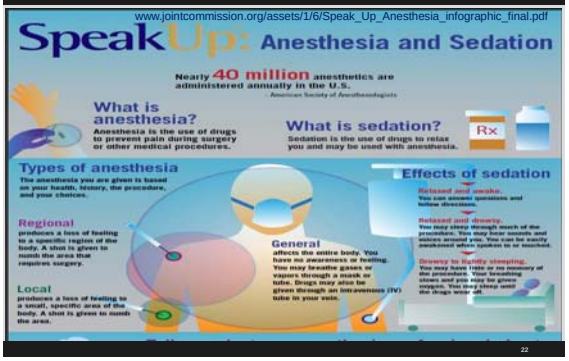
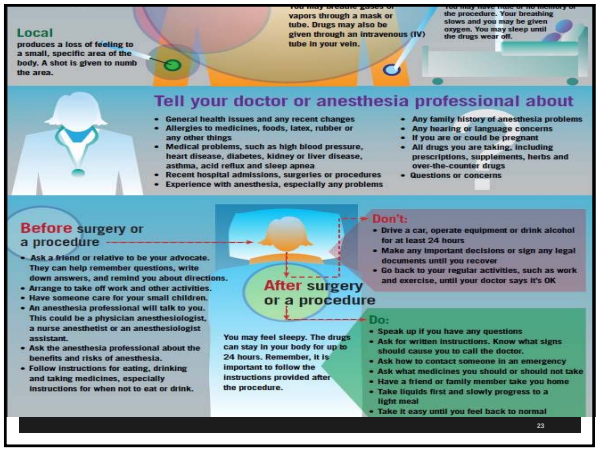
TJC Speak Up Poster Anesthesia & Sedation





Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Will update quarterly
  - Available under downloads on the hospital website at www.cms.gov

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Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-21- ALL

DATE: March 22, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals

Memorandum Summary

- ***Survey Findings Posted on*** *http://www.cms.gov:* In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on *Nursing Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.
- ***Other Web-based Tools Based on These Data:*** At least two additional websites, provided by private parties (*ProPublica* and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- ***Plans of Correction (POC):*** The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.
- ***Question & Answers:*** We plan to issue an update to this memorandum that will include an attachment of frequently asked questions in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Form

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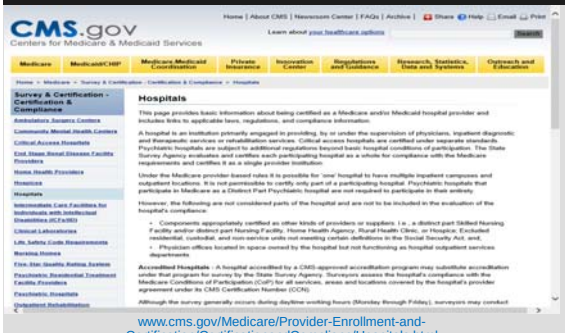
Updated Deficiency Data Reports



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Home > Medicare > Survey & Certification - Certification & Compliance > Hospitals

Survey & Certification - Certification & Compliance

- Ambulatory Surgery Centers
- Community Mental Health Centers
- Critical Access Hospitals
- End Stage Renal Disease Facility Providers
- Home Health Providers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)
- Clinical Laboratories
- Life Safety Code Requirements
- Nursing Homes
- Five-Star Quality Rating System
- Psychiatric Residential Treatment Facility Providers
- Psychiatric Hospitals
- Outpatient Rehabilitation

Hospitals

This page provides basic information about being certified as a Medicare and/or Medicaid hospital provider and includes links to applicable laws, regulations, and compliance information.

A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services. Critical access hospitals are certified under separate standards. Psychiatric hospitals are subject to additional regulations beyond basic hospital conditions of participation. The State Survey Agency evaluates and certifies each participating hospital as a whole for compliance with the Medicare requirements and certifies it as a single provider institution.

Under the Medicare provider-based rules it is possible for 'one' hospital to have multiple inpatient campuses and outpatient locations. It is not permissible to certify only part of a participating hospital. Psychiatric hospitals that participate in Medicare as a Distinct Part Psychiatric hospital are not required to participate in their entirety.

However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital's compliance:

- Components appropriately certified as other kinds of providers or suppliers. I.e., a distinct part Skilled Nursing Facility and/or distinct part Nursing Facility, Home Health Agency, Rural Health Clinic, or Hospice; Excluded residential, custodial, and non-service units not meeting certain definitions in the Social Security Act, and,
- Physician offices located in space owned by the hospital but not functioning as hospital outpatient services departments

Accredited Hospitals - A hospital accredited by a CMS-approved accreditation program may substitute accreditation under that program for survey by the State Survey Agency. Surveyors assess the hospital's compliance with the Medicare Conditions of Participation (CoP) for all services, areas and locations covered by the hospital's provider agreement under its CMS Certification Number (CCN).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

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Anesthesia Deficiencies

Section	Tag Number	July 15, 2015
Anesthesia Services	1000	12
Organization of Anesthesia	1001	1
Delivery Anesthesia Services	1002	9
Pre-Anesthesia Evaluation	1003	21
Intra-Operative Record	1004	7
Post Anesthesia Evaluation	1005	25 Total 74

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CMS Manual and Anesthesia Changes

- All the manuals are now located at
  - www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf
  - There were four anesthesia revisions over a 2 year period of time
  - **CAH standards** are different and at the end
- Three were published in survey and certification website and one in a transmittal
  - December 11, 2009
  - February 5, 2010
  - May 21, 2010 (transmittal) and
  - February 14, 2011

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Location of CMS Hospital CoP Manual

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

CMS CoP Manuals are now located at
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

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First and Second of Four Anesthesia Changes

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-09-Hospital
REVISED 2-05-2010

DATE: December 11, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Anesthesia Services Interpretive Guidelines – State Operations Manual (SOM) Appendix A

www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

****Attached guidelines include corrections to figure on page 2 and monitored anesthesia care (MAC) section on page 3****

Memorandum Summary

- **Hospital Anesthesia Services Requirements Clarified** – The Centers for Medicare & Medicaid Services (CMS) is clarifying the interpretive guidelines (IGs) for the Hospital Condition of Participation (CoP) governing Anesthesia Services.
- **Types of Anesthesia Services** - The guidance indicates which types of anesthesia services are subject to the requirements governing administration of anesthesia specified at 42 CFR 482.52.
- **Anesthesia Requirements** - Further details on the pre-, intra- and post-operative anesthesia requirements are also provided.

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May 21, 2010 CMS Transmittal 59 3rd Change

www.cms.gov/Transmittals/01_overview.asp

CMS Manual System
Pub. 100-07 State Operations Provider Certification
Transmittal 59

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Date: May 21, 2010

SUBJECT: Clarification of the Interpretive Guidelines for the Anesthesia Services Condition of Participation

I. SUMMARY OF CHANGES: Revisions to Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals." This instruction updates and clarifies the guidance for the Anesthesia Services Condition of Participation and related standards.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 21, 2010
IMPLEMENTATION DATE: May 21, 2010

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: ***(N/A if manual not updated.)***
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.52/Condition of Participation Anesthesia Services/ Tag A-1000
R	Appendix A/§482.52(a)/Standard: Organization and Staffing/Tag A-1001
R	Appendix A/§482.52(b)/Standard: Delivery of Services/Tag A-1002
R	Appendix A/§482.52(b)(1)/Standard: Pre-anesthesia Evaluation/Tag A-1003
R	Appendix A/§482.52(b)(2)/Standard: Intraoperative Anesthesia Record/Tag A 1004

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4th Changes January 14, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare& Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-01
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-11-10-Hospitals

DATE: **January 14, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Anesthesia Services Interpretive Guidelines—State Operations Manual (SOM) Appendix A

www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

Memorandum Summary

Revisions to Recently Updated Interpretive Guidelines for Anesthesia Services: The Centers for Medicare & Medicaid Services (CMS) has revised the guidelines concerning the anesthesia services Condition of Participation (CoP) at 42 CFR 482.52.

- Hospitals are expected to develop and implement policies and procedures that address the clinical circumstances under which medications that fall along the analgesia-anesthesia continuum are considered anesthesia, and specify the qualifications of practitioners who can administer analgesia.
- Additional clarifications related to pre- and post-anesthesia evaluation requirements are provided.
- Frequently Asked Questions (FAQs) are also attached.

On December 11, 2009 CMS released updated Interpretive Guidelines for the Anesthesia Services Condition of Participation (CoP) for Hospitals as an attachment to S&C memo 10-09. Among other things, this guidance was a response to requests for clarification of the distinction between analgesia

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Transmittal and Final Wording Dec 2, 2011

A-1000

(Rev.74, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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 §482.52

The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

"Anesthesia" involves the administration of a medication to produce a blunting or loss of:

- pain perception (analgesia);
- voluntary and involuntary movements;
- autonomic function; and
- memory and/or consciousness,

depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.

In contrast, "analgesia" involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not

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CMS Hospital CoPs

- Interpretative guidelines under state operations manual[1]
  - Appendix A, Tag A-**0001** to A-**1164** and 456 pages long
  - Anesthesia section starts at tag number **1000** and goes **to 1005**
  - January 14, 2011 memo makes extensive changes especially to 3 tag numbers, 1000, 1003, and 1005
- Every hospital should have a copy of the CMS manual consider placing on the intranet and this is where all the manuals are located (new website)

[1] www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

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CMS Anesthesia Standards Changes

- Hospitals are expected to have P&P on when medications that fall along the analgesia-anesthesia continuum are considered anesthesia
  - P&P must be based on nationally recognized guidelines
- Must specify the qualifications of practitioners who can administer analgesia
- CMS further clarified pre-anesthesia and post-anesthesia evaluations
- CMS added FAQs which are very helpful
  - Hospitals should review these as many changes and clarifications were made

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CMS Anesthesia Standards Changes

- CMS has added additional requirements for the definition and use of analgesia (pain) through out the hospital
- These are less prescriptive than the prior changes
- CMS requires the hospital to develop policies on specific clinical privileges involving anesthesia and analgesia (pain)
- Must specify the qualifications for each category of practitioners who administer analgesia
- Strong emphasis on rescue capacity of hospitals

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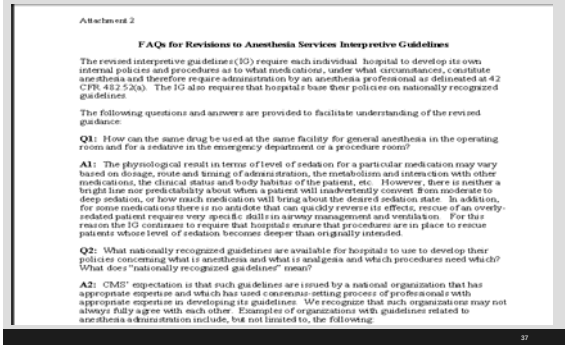
CMS Added Six FAQs



Attachment 2

FAQs for Revisions to Anesthesia Services Interpretive Guidelines

The revised interpretive guidelines (IG) require each individual hospital to develop its own internal policies and procedures as to what medications, under what circumstances, constitute anesthesia and therefore require administration by an anesthesia professional as delineated at 42 CFR 482.52(a). The IG also requires that hospitals base their policies on nationally recognized guidelines.

The following questions and answers are provided to facilitate understanding of the revised guidance:

Q1: How can the same drug be used at the same facility for general anesthesia in the operating room and for a sedative in the emergency department or a procedure room?

A1: The physiological result in terms of level of sedation for a particular medication may vary based on dosage, route and timing of administration, the metabolism and interaction with other medications, the clinical status and body habitus of the patient, etc. However, there is neither a bright line nor predictability about when a patient will inadvertently convert from moderate to deep sedation, or how much medication will bring about the desired sedation state. In addition, for some medications there is no antidote that can quickly reverse its effects, rescue of an overly-sedated patient requires very specific skills in airway management and ventilation. For this reason the IG continues to require that hospitals ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than originally intended.

Q2: What nationally recognized guidelines are available for hospitals to use to develop their policies concerning what is anesthesia and what is analgesia and which procedures need which? What does "nationally recognized guidelines" mean?

A2: CMS' expectation is that such guidelines are issued by a national organization that has appropriate expertise and which has used consensus-setting process of professionals with appropriate expertise in developing its guidelines. We recognize that such organizations may not always fully agree with each other. Examples of organizations with guidelines related to anesthesia administration include, but not limited to, the following:

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Sample Page from CMS Manual

A-1000

(Rev. 74, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§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.

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"Anesthesia" involves the administration of a medication to produce a blunting or loss of:

- pain perception (analgesia);
- voluntary and involuntary movements;

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Introduction

- Divides into two buckets which are the anesthesia and analgesia (pain)
- Analgesia (pain) is bucket one and includes 4 things; Topical, local, moderate and minimal sedation
  - Patient does not lose consciousness (Tag 1000)
  - CRNA or anesthesiologist not required
  - No requirement for preanesthesia or post anesthesia assessment but would want to do an assessment
  - TJC has standards in the PC chapter on pre-sedation and post-sedation evaluation and this is the standard of care (SOC)

39

Introduction

- Bucket one analgesia or pain (continued)
  - CMS removes language that says administration of epidural or spinal during labor and delivery is not subject to the anesthesia standard
- Need policy on who can do analgesia such as PA, NP, or RN
  - PA, physician or NP may give local with Lidocaine to suture in the ED
  - RN may give Valium 2.5 mg to patient before MRI
  - RN may help with moderate sedation in the ED or GI lab

40

Introduction

- Anesthesia is bucket two and includes:
  - General, epidural and spinal (regional), MAC, and deep sedation by one qualified to give anesthesia such as
    - CRNA , Anesthesiologist, or Anesthesiology Assistant (AA)
    - Dentist, podiatrist, or oral surgeon allowed within scope of practice
    - Does say physician other than anesthesiologist but must be qualified such as an ED or GI physician
  - Preanesthesia and post anesthesia evaluation required by anesthesia provider and must document elements required
  - CMS also has what must be documented during surgery by anesthesia provider and adds requirements so make sure your form to include these

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Anesthesia 1000

- Must be provided in well organized manner under qualified doctor
  - Final revision changed the section on the criteria for the qualification of the anesthesia director
  - Service responsible for all anesthesia administered in the hospital
- Optional service and must be integrated into hospital QAPI

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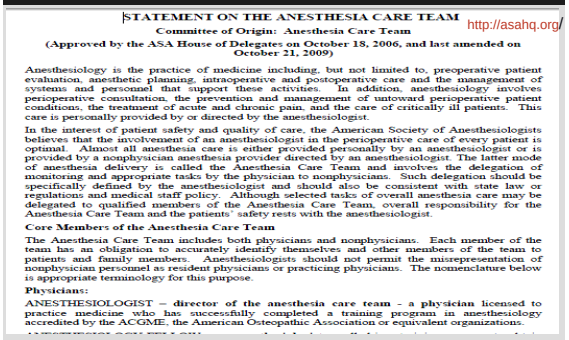
ASA Position on Director of Anesthesiology



STATEMENT ON THE ANESTHESIA CARE TEAM

Committee of Origin: Anesthesia Care Team

(Approved by the ASA House of Delegates on October 18, 2006, and last amended on October 21, 2009)

Anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel that support these activities. In addition, anesthesiology involves perioperative consultation, the prevention and management of untoward perioperative patient conditions, the treatment of acute and chronic pain, and the care of critically ill patients. This care is personally provided by or directed by the anesthesiologist.

In the interest of patient safety and quality of care, the American Society of Anesthesiologists believes that the involvement of an anesthesiologist in the perioperative care of every patient is optimal. Almost all anesthesia care is either provided personally by an anesthesiologist or is provided by a nonphysician anesthesia provider directed by an anesthesiologist. The latter mode of anesthesia delivery is called the Anesthesia Care Team and involves the delegation of monitoring and appropriate tasks by the physician to nonphysicians. Such delegation should be specifically defined by the anesthesiologist and should also be consistent with state law or regulations and medical staff policy. Although selected tasks of overall anesthesia care may be delegated to qualified members of the Anesthesia Care Team, overall responsibility for the Anesthesia Care Team and the patients' safety rests with the anesthesiologist.

Core Members of the Anesthesia Care Team

The Anesthesia Care Team includes both physicians and nonphysicians. Each member of the team has an obligation to accurately identify themselves and other members of the team to patients and family members. Anesthesiologists should not permit the misrepresentation of nonphysician personnel as resident physicians or practicing physicians. The nomenclature below is appropriate terminology for this purpose.

Physicians:

ANESTHESIOLOGIST – director of the anesthesia care team - a physician licensed to practice medicine who has successfully completed a training program in anesthesiology accredited by the ACGME, the American Osteopathic Association or equivalent organizations.

http://asahq.org/

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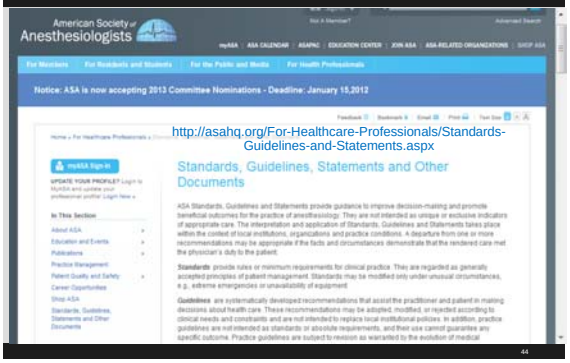
ASA Guidelines and Standards



http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

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Anesthesia A-1000

- **Anesthesia** involves administration of medication to produce a blunting or loss of;
  - Pain perception (analgesia)
  - Voluntary and involuntary movements
  - Autonomic function
  - Memory and or consciousness
- **Analgesia** (pain) is use of medication to provide pain relief thru blocking pain receptor in peripheral and or CNS where patient does not lose consciousness but does not perceive pain.

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Anesthesia 1000

- Anesthesia exists on a continuum
- There is not a bright line that distinguishes when the drug's properties from analgesia to anesthesia
- CMS has definitions of what constitutes general anesthesia and , regional, monitored anesthesia care (MAC), and deep sedation
- For the most part, definitions follow the ASA practice guidelines
  - Anesthesiology 2002; 96:1004-17

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- **General anesthesia**: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services;
- **Regional anesthesia**: the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is necessary that the administration of regional and general anesthesia be delivered or supervised by a practitioner as specified in 42 CFR 482.52(a).

Copyright

Monitored Anesthesia Care (MAC)

- Monitored Anesthesia Care (MAC) that includes monitoring of patient by a person qualified to give anesthesia (like anesthesiologist or CRNA)
- Include potential to convert to a general or regional anesthetic
- Deep sedation/analgesia is included in a MAC
- Deep sedation where drug induced depression of consciousness during which patient can not easily be aroused but responds purposefully following repeated or painful stimulus
  - Removed : An example of deep sedation is when Propofol is used for a screening colonoscopy

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Definition of MAC by CMS

- **Monitored anesthesia care (MAC)**: anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC.
  - Deep sedation/analgesia: a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner as specified in 42 CFR 482.52(a).

Anesthesia Services 1000

- Services **not** subject to anesthesia administration and supervision requirements
  - Topical or local anesthesia ; application or injection of drug to stop a painful sensation
  - Minimal sedation; drug induced state in which patient can respond to verbal commands such as oral medication to decrease anxiety for MRI
  - Moderate or conscious sedation; in which patients respond purposely to verbal commands, either alone or by light tactile stimulation

Definitions of Analgesia (Pain)

- **Moderate sedation/analgesia: ("Conscious Sedation"):** *a* drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia (71FR 68690-1).
- **Minimal sedation**: *a* drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia.
- **Topical or local anesthesia**: *the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name.*

Anesthesia Services 1000

- Rescue capacity
  - Sedation is a continuum
  - It is not always possible to predict how any individual patient will respond
  - So may need to rescue by one with expertise in airway management and advanced life support
  - Must have procedures in place to rescue patients whose sedation becomes deeper than initially intended

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Anesthesia Services 1000

- TJC has standards also on how to safely perform moderate or procedural sedation and anesthesia in the PC chapter and located at end of slides
- Still need to do a pre-sedation assessment and post-sedation assessment but since not anesthesia not a pre or post-anesthesia assessment
- Also references the need to follow nationally standards of practice such as ASA (American Society of Anesthesiologists), ACEP (American College of Emergency Physicians) and ASGE (American Society for GI Endoscopy), AGA, ENA, ADA, etc.
  - Listed at the end as additional resources

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One Anesthesia Service 1000

- Anesthesia services must be under one anesthesia services under direction of qualified physician no matter where performed through out the hospital
- Including if done in any of the following:
  - Operating room for both inpatients and outpatients
  - OB
  - Radiology (interventional radiology), clinics (pain clinic),
  - ED
  - Psychiatry (ECT)
  - Endoscopy, pain management clinics etc.

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Anesthesia Services under Qualified Director

- Anesthesia services must be under the direction of one individual who is a qualified doctor (1000)
- Need to have medical staff rules and regulations establishing the criteria for the qualifications for the director of anesthesia services
- MS establishes this criteria for director's qualifications
- The board approves after consideration of the medical staff's recommendation
- Must be consistent with state law and acceptable standards of practice

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Interpretation from CMS

- The regulation states, "…under the direction of a qualified doctor of medicine or osteopathy." This means the anesthesia service can be directed by any type of MD or DO who is qualified.
- You are correct that in most hospitals with an anesthesia service, an anesthesiologist would "generally" be the director. However, some hospitals do not have an anesthesiologist on staff. If a hospital provides any type of anesthesia service, the hospital would have to find an MD or DO that has the **qualifications** to be the Director of Anesthesia Services in the hospital.
- The hospital would establish criteria for determining that a particular MD or DO was qualified to be the director (such as knowledge of anesthesia procedures, anesthesia/sedation/analgesia medications, State scope of practice rules, National Standards of practice, administrative skills, management, and other criteria). Hospitals already must establish criteria for determining whether a physician is qualified to provide care and which types of care. Therefore, a hospital should be able to ensure that whichever MD or DO they select as the Director of Anesthesia Services is qualified for that position.

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CMS Manual Anesthesia One Service

The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO). Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital's governing body approves, after considering the medical staff's recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria must be consistent with State laws and acceptable standards of practice.

57

Anesthesia Services Who Can Give? 1000

- Hospital needs to have policies and procedures that are based on nationally recognized guidelines as to whether it is anesthesia or analgesia
  - Be sure to cite standard such as ASA, ASGE, ACEP etc.
- Hospitals need to determine if sedation done in the ED or procedures rooms is anesthesia or analgesia
- Must take into consideration for P&P characteristics of patients served, skill set of staff and what medications are being used
- This standard also sets forth the supervision requirements for staff who administer anesthesia

58

Supervision and Privileges 1000

- P&Ps need to establish minimum qualifications and supervision requirements including moderate sedation
  - MS credentialing standards and the nursing standards exist to make sure staff are qualified and competent
  - Want to make sure that staff administering drugs are qualified
  - Drugs must be given with accepted standards of practice
  - MS bylaws address criteria for determining privileges and to apply the criteria to those who request privileges

59

Supervision and Privileges 1000

- If nursing staff give IV medication then must be competent in specified areas
  - Amended June 6, 2014 so follow P&P
  - This is one of the education requirements of CMS
  - Also training on restraint and seclusion, infection control and hand hygiene, abuse and neglect, advance directives, organ donation, IV and blood and blood products and ED staff with ED common emergencies, timing of medication, medication error, safe opioid use, ADE and drug incompatibilities
- Must have P&P to look at adverse events, medication errors and other safety and quality indicators
  - Must periodically re-evaluate these and include in PI

60

Blood Transfusions and IVs 409 2014

- Standard: Blood transfusions and IV medications must be administered with state law and MS bylaws
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- CMS eliminated the regulations mandating training for non-physicians who administer IV medication and blood and blood products
  - CMS says because this training is already standard practice but must still be competent in those areas
  - Must follow your P&P and state scope of practice

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Blood and IV Medication Training 2013

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

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Anesthesia Services 1000

- Hospital Medical Staff determine the qualifications for the Director of Anesthesia
- Must be in accordance with the state law and acceptable standards of practice
- Anesthesia service is responsible for developing policies and procedures governing all categories of anesthesia service
- This includes the minimum qualification for each category of practitioner who is permitted to provide anesthesia services

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Anesthesia Survey Procedure 1000

- Surveyor is suppose to ask for a copy of the organizational chart for anesthesia
- Make sure MD or DO has authority and responsibility for directing anesthesia services throughout the hospital
- Anesthesia must be integrated into the QAPI program
  - Every department has a role in PI including anesthesia
  - See Anesthesia Quality Institute (AQI) which is home to national anesthesia clinical outcomes registry (NACOR) and has list of things to measure

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What PI Do You Measure?

Process indicators: on time starting, prophylactic antibiotic administration, adherence to central line bundle, normothermia in the PACU, number of patient complaints

Are anesthesia staff educated on the CMS grievance and TJC Complaint standard?
Yes__No__

Clinical outcome indicators-patient satisfaction, number of cases completed without any event, number of each critical event occurring by location (high spinal, epidural hematoma, infection after regional, perioperative MI, death, unplanned difficult airway, local anesthesia toxicity, medication error, incorrect patient, OR fire, transfusion reaction, new stroke, visual loss, Intraoperative awareness, peripheral neurologic deficit, etc)

CMS 2011 outpatient surgical measure is antibiotic timing and is described by CMS as "Percentage of outpatients having surgery who were given the right kind of antibiotic at the right time (within one hour before surgery) to help prevent infection of surgical wounds." This measure is already in place for inpatient data and will be used in conjunction to obtain a more comprehensive view of the quality of care being provided in hospitals.

Case information; no untoward event, significant delay, case cancelled, equipment problem, extended PACU stay, unanticipated ICU admission, unanticipated hospital admission, death, cardiac arrest, anaphylaxis, malignant hyperthermia, transfusion reaction, visual loss, stroke, PONV, PACU pain control in adequate, hypotension or hypothermia in the PACU, vascular access complication, infection after regional anesthesia, high spinal, postdural puncture headache,

65

What Do You Measure?

Reason for Review
An-1 CNS complication
An-2 Peripheral neurologic deficit
An-3 AMI post anesthesia
An-4 Cardic Arrest post anesthesia
An-5 Respiratory Arrest post anesthesia
An-6 Death w/in 48 hous of anesthesia
An-7 Unplanned adm w/in 24 hours d/t anesthesia
An-8 Unplned adm to ICU w/in 24 hours of anes
An-9 Pulmonary Edema w/in 24 hrs of anesthesia
An-10 Aspiration pneumonitis w/in 48 hours
An-13 Anesthesia Awareness
M-1 Death w/i 48 hours of surgical/invasive proc
M-2 Intra-operative death
M-3 Death w/i immediate recover time of surg/inv
M-4 Death w/i 48 hours of IV sedation
S-1 Unscheduled admission following outpt proc

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What Do You Measure?

S-1 Unscheduled admission following outpt proc
S-2 Unplanned return to surgery
S-3 Foreign object/material found/left in wound
S-4 Burn or non-surgical trauma
S-5 Wrong procedure or wrong pt
S-9 Nerve damage noted post-operatively
S-12 Any untoward patient reaction in OR/PACU/ENDO
S-16 Post Operative Complication
S-17 Path/operative dx mismatch
S-20 Accidental puncture or laceration during proc
S-23 Mismatch pre and post op diagnosis
ModSed-1 Reversal Agent Administered
ModSed -2 Hemodynamic Instability
ModSed -3 Extended recovery time
ModSed -4 Unplanned Admission
ModSed -5 Unplanned Surgery
ModSed-7 Decreased O2 Sat

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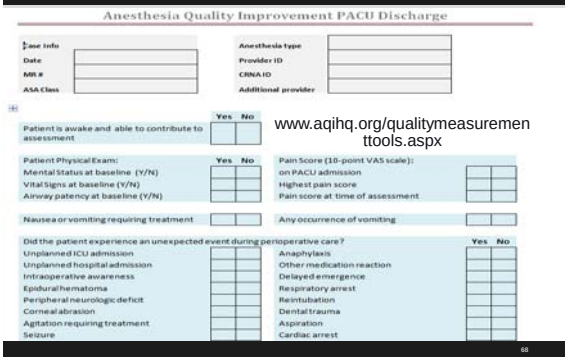
AQI Has Data Capture Sheets


Anesthesia Quality Improvement PACU Discharge

Case Info
Date
MR #
ASA Class

Anesthesia type
Provider ID
CRNA ID
Additional provider

Yes No

Patient is awake and able to contribute to assessment

Patient Physical Exam:
Mental Status at baseline (Y/N)
Vital Signs at baseline (Y/N)
Airway patency at baseline (Y/N)

Pain Score (10-point VAS scale):
on PACU admission
Highest pain score
Pain score at time of assessment

Nausea or vomiting requiring treatment

Any occurrence of vomiting

Did the patient experience an unexpected event during perioperative care?

Unplanned ICU admission
Unplanned hospital admission
Intraoperative awareness
Epidural hematoma
Peripheral neurologic deficit
Corneal abrasion
Agitation requiring treatment
Seizure

Anaphylaxis
Other medication reaction
Delayed emergence
Respiratory arrest
Reintubation
Dental trauma
Aspiration
Cardiac arrest

www.aqihq.org/qualitymeasurementtools.aspx

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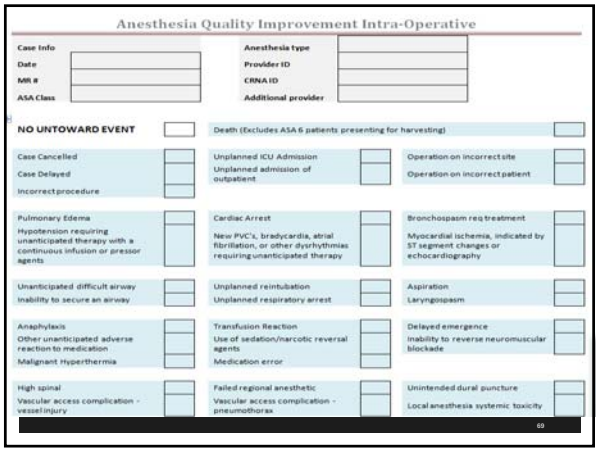
Anesthesia Quality Improvement Intra-Operative

Case Info
Date
MR #
ASA Class

Anesthesia type
Provider ID
CRNA ID
Additional provider

NO UNTOWARD EVENT

Death (Excludes ASA 6 patients presenting for harvesting)

Case Cancelled
Case Delayed
Incorrect procedure

Unplanned ICU Admission
Unplanned admission of outpatient

Operation on incorrect site
Operation on incorrect patient

Pulmonary Edema
Hypotension requiring unanticipated therapy with a continuous infusion or pressor agents

Cardiac Arrest
New PVC's, bradycardia, atrial fibrillation, or other dysrhythmias requiring unanticipated therapy

Bronchospasm req treatment
Myocardial ischemia, indicated by ST segment changes or echocardiography

Unanticipated difficult airway
Inability to secure an airway

Unplanned reintubation
Unplanned respiratory arrest

Aspiration
Laryngospasm

Anaphylaxis
Other unanticipated adverse reaction to medication
Malignant Hyperthermia

Transfusion Reaction
Use of sedation/narcotic reversal agents
Medication error

Delayed emergence
Inability to reverse neuromuscular blockade

High spinal
Vascular access complication - vessel injury

Failed regional anesthetic
Vascular access complication - pneumothorax

Unintended dural puncture
Local anesthesia systemic toxicity

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AQI Core Measures Outcomes of Anesthesia

Intraoperative Events.

- Death (Excludes ASA 6 patients presenting for organ harvest)
- Cardiac
  - Cardiac arrest
  - New PVCs, bradycardia, atrial fibrillation, or other dysrhythmias requiring unanticipated therapy
  - Myocardial ischemia, indicated by ST segment changes or echocardiography
  - Hypotension requiring unanticipated therapy with a continuous infusion of pressor agents
  - Pulmonary edema
- Respiratory
  - Unanticipated difficult airway
  - Inability to secure an airway
  - Unplanned reintubation
  - Unplanned respiratory arrest
  - Aspiration
  - Laryngospasm
  - Bronchospasm requiring unanticipated treatment
- Medication
  - Anaphylaxis
  - Other unanticipated adverse reaction to a medication
  - Malignant hyperthermia
  - Transfusion reaction
  - Medication error
  - Use of sedation/narcotic reversal agents (e.g. flumazenil, naloxone)
  - Inability to reverse neuromuscular blockade
  - Delayed emergence
- Procedural
  - Vascular access complication: vessel injury
  - Vascular access complication: pneumothorax
  - High spinal
  - Local anesthesia systemic toxicity
  - Failed regional anesthetic
  - Unintended dural puncture

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Anesthesia Survey Procedure 1000

- Surveyor to look in directors file
- Will review job or position description of MD/DO director and look for appointment
- Will make sure privileges and qualifications are consistent with the criteria adopted by the board
- Will confirm directors responsibilities include;
  - Planning, directing, and supervision of all activities
  - Removed section on establishing staffing schedules
  - Evaluate the quality and appropriateness of anesthesia services provided to patients as part of PI process

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Anesthesia Survey Procedure 1000

- Surveyor is suppose to request and review all of the anesthesia policies and procedures
- Will make sure the anesthesia apply to every where in the hospital where anesthesia services are provided
- Will make sure the P&P 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

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Anesthesia Survey Procedure 1000

- Surveyor is to make sure that the clinical applications are considered involving analgesia such as moderate sedation as opposed to anesthesia
- Document what national guidelines are being followed
- See the FAQ on this which will be discussed later
- The surveyor will make sure the hospital has an adverse event system related to both anesthesia and analgesia
  - Are they tracked and acted upon (incident report, RCA, etc.)

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5 Qualified to Give Anesthesia 1001

- Anesthesia (general, regional, MAC including deep sedation) can only be administered by;
  - Qualified anesthesiologist or CRNA
  - Anesthesiology assistant (AA) under the supervision of anesthesiologist who is immediately available if needed
  - Dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law
  - A MD or DO other than anesthesiologist (must be qualified)
    - Lots of discussion on this
    - Hospital needs to follow standards of anesthesia care when establishing P&P *governing* anesthesia administration by these types of practitioners as well as MDs or DOs who are **not** anesthesiologists

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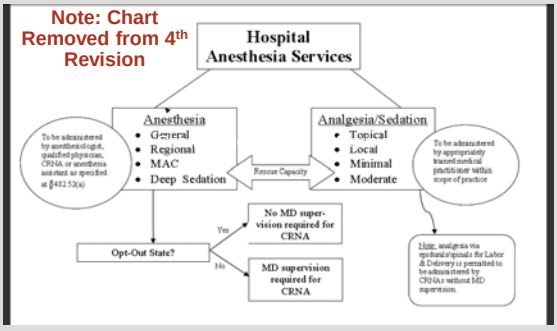
Who Is Qualified to Give Anesthesia

Note: Chart Removed from 4th Revision



75

Who Can Administer Anesthesia

Administration by an MD/DO/dentist/oral surgeon/podiatrist

The hospital's anesthesia services policies must address the circumstances under which an MD or DO who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications. Hospitals should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists.

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Organization and Staffing 1001

- CRNA can be supervised by the operating surgeon or the anesthesiologist
- CRNA may not require supervision if state got an exemption from supervision[1]
- Governor sends a letter to CMS requesting this after attesting that the State Medical Board and Nursing Board were consulted and in best interests of the state
- List of 17 state exemptions at www.cms.hhs.gov/CFCsAndCoPs/02_Spotlight.asp
  - Iowa, Nebraska, Kentucky, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, South Dakota, Wisconsin, Montana, Colorado, and California

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Administering 1001

- Need P&P concerning who may administer analgesia
  - Topical, local, minimal sedation and moderate sedation
  - Consistent with scope of practice set by state law
- General, regional, MAC and deep sedation can only be administered by the 5 categories mentioned
- Hospital must follow generally accepted standards of anesthesia care if anyone other than anesthesiologist, CRNA, or AA does
- Need policy on supervision also

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Who Can Administer Anesthesia 1001

- CRNA can administer anesthesia if under the operating surgeon or by an anesthesiologist
- If supervised by an anesthesiologist must be **immediately available**
- What does immediately available mean?
- Anesthesiologist must be physically located in the same area as the CRNA
- Example: in the same operative suite , same procedure room, same L&D unit and nothing prevents from immediate hands on intervention

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CRNA Supervision

- No supervision if in one of the 17 states that has opted out and so no longer requires it
- Otherwise must be supervised by
  - Operating practitioner who is performing the procedure or
  - Anesthesiologist who is immediately available
- Immediately available means anesthesiologist must be located within the same area of the CRNA and not occupied to prevent him/her from immediately conducting hands on intervention if needed
  - If CRNA in OR then anesthesiologist must be somewhere in the OR suite

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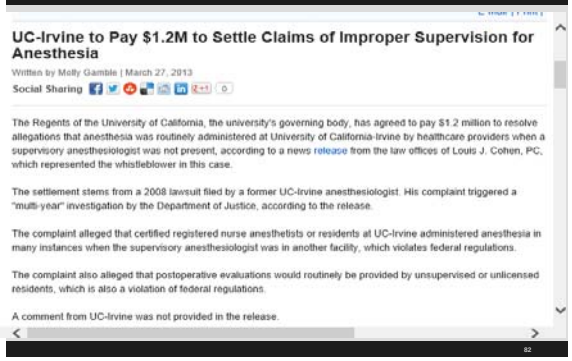
Administration by a CRNA

Unless the hospital is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

Hospitals should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner. 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 suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

Don't Want a False Claims Act Lawsuit



UC-Irvine to Pay $1.2M to Settle Claims of Improper Supervision for Anesthesia

Written by Molly Gamble | March 27, 2013

Social Sharing

The Regents of the University of California, the university's governing body, has agreed to pay $1.2 million to resolve allegations that anesthesia was routinely administered at University of California-Irvine by healthcare providers when a supervisory anesthesiologist was not present, according to a news release from the law offices of Louis J. Cohen, PC, which represented the whistleblower in this case.

The settlement stems from a 2008 lawsuit filed by a former UC-Irvine anesthesiologist. His complaint triggered a "multi-year" investigation by the Department of Justice, according to the release.

The complaint alleged that certified registered nurse anesthetists or residents at UC-Irvine administered anesthesia in many instances when the supervisory anesthesiologist was in another facility, which violates federal regulations.

The complaint also alleged that postoperative evaluations would routinely be provided by unsupervised or unlicensed residents, which is also a violation of federal regulations.

A comment from UC-Irvine was not provided in the release.

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Improper Supervision of Anesthesia Services

- A federal qui tam whistle blower lawsuit was filed by former anesthesiologist and professor Dr. Dennis O'Connor
- Investigated by the US Dept of Justice
- Hospital in California pays $1.2 million to resolve claims of improper supervision of anesthesia services
- Said no supervisory anesthesiologist was present or immediately available in violation of federal law
- Anesthesia records pre-filled out to make it look like anesthesiologist were there

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Anesthesiology Assistant 1001

- Some states have a practice act for AAs or anesthesiology assistants
- An AA may administer anesthesia only when under the direct supervision of an anesthesiologist only
- Anesthesiologist must also be immediately available if needed
- This means physically in the same department and not occupied in a way to prevent immediate hands on intervention if needed

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Administration by an anesthesiologist's assistant

An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed. An anesthesiologist is considered "immediately available" to assist the anesthesiologist's assistant under the anesthesiologist's supervision only if he/she is physically located within the same area as the anesthesiologist's assistant, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

An anesthesiologist's assistant is defined in §410.69(b) as a "…person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background."

85

http://anesthesiaassistant.com

86

Anesthesia Services Policies 1001

- MS bylaws or R/R must include criteria for determining anesthesia privileges
- Board must approve the specific anesthesia service privilege for each practitioner who does anesthesia services
- Must address the type of supervision required, if any, and must specify who can supervise CRNA (unless exempted)
- Privileges must be granted in accordance with state law and hospital policy

87

Supervision by Operating Practitioner 1002

- If hospital allows supervision by operating practitioner of CRNAs
  - Such as surgeons, podiatrist, or gastroenterologist
- Medical staff bylaws or R/R must specify for each category of operating practitioners
- The type and complexity of the procedures that the category of practitioner may supervise
- See resources at the end that discuss standards of practice on credentialing and privileging

88

Survey Procedure 1001

- Surveyor is to review the qualifications of individuals allowed to give anesthesia to make sure they are qualified
- Make sure licenses and certifications are current
- Determine if state has opted out for CRNA supervision
- Review the hospital P&P to make sure supervision of CRNA and AA meets requirements
- Review qualifications of other anesthesia services to make sure they are consistent with the hospital anesthesia policies

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Anesthesia Services and Policies 1002

- Anesthesia must be consistent with needs of patients and resources
- P&P must include delineation of pre-anesthesia and post-anesthesia responsibilities
- Must be consistent with the standards of care
- Policies include;
  - Consent
  - Infection Control measures
  - Safety practices in all areas
  - How hospital anesthesia service needs are met

90

Anesthesia Policies Required 1002

- Policies required (continued);
  - Protocols for life support function such as cardiac or respiratory emergencies
  - Reporting requirements
  - Documentation requirements
  - Equipment requirements
  - Monitoring, inspecting, testing and maintenance of anesthesia equipment
  - Pre and post anesthesia responsibilities

91

Pre-Anesthesia Assessment 1003

- Pre-anesthesia evaluation must be performed with 48 hours prior to the surgery
  - Including inpatient and outpatient procedures
- For regional, general, and MAC
- Not required for moderate sedation but still need to do pre sedation assessment
- Preanesthesia assessment must be done by some one qualified person to administer anesthetic (non-delegable)

92

Pre-Anesthesia Evaluation 1003

- Must have policies to make sure the pre-anesthesia guidelines are met
- Pre-anesthesia evaluation must be completed, documented and done by one qualified to administer anesthesia within 48 hours
  - Can not delegate the pre-anesthesia assessment to someone who is not qualified which is 5 categories mentioned
  - Must be done within 48 hours of surgery or procedure

93

5 Qualified to do Pre-Anesthesia Assessment

- Anesthesiologist
- CRNA under the supervision of operating surgeon or anesthesiologist unless state is exempt
- AA under supervision of anesthesiologist
- MD or DO other than an anesthesiologist
- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law

94

Pre-Anesthesia Evaluation 1003

- Delivery of first dose of medication for inducing anesthesia marks end of **48 hour** time frame
- Pre-anesthesia assessment must be done for generals, regional, or MAC which includes deep sedation
- If moderate sedation current practice dictates a pre-procedure assessment but not a pre-anesthesia assessment
- See TJC standards at the end of presentation on presedation assessment for patients having moderate sedation

95

Pre-Anesthesia Evaluation 1003

- CMS says pre-anesthesia must be done within 48 hours of procedure or surgery
- However, some of the elements in the evaluation can be collected prior to the 48 hours time frame but it can never be more than 30 days (new)
  - If you saw a patient on Friday for Monday surgery would need to show that on Monday there were no changes
  - CMS also specifies the four of the six required elements that can be performed within 30 days

96

Pre-Anesthetic Assessment 1003

- Must include;
  - Review of medical history, including anesthesia, drug, and allergy history (within 48 hours)
  - Interview and exam the patient
    - Within 48 hours and rest are updated in 48 hours but can be collected within 30 days
  - Notation of anesthesia risk (such as ASA level)
  - Potential anesthesia problems identification (including what could be complication or contraindication like difficult airway, ongoing infection, or limited intravascular access)

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Pre-Anesthetic Assessment 1003

- Pre-anesthetic Assessment to include (continued);
  - Additional data or information in accordance with SOC or SOP
    - Including information such as stress test or additional consults
  - Develop plan of care including type of medication for induction, maintenance, and post-operative care
  - Of the risks and benefits of the anesthesia

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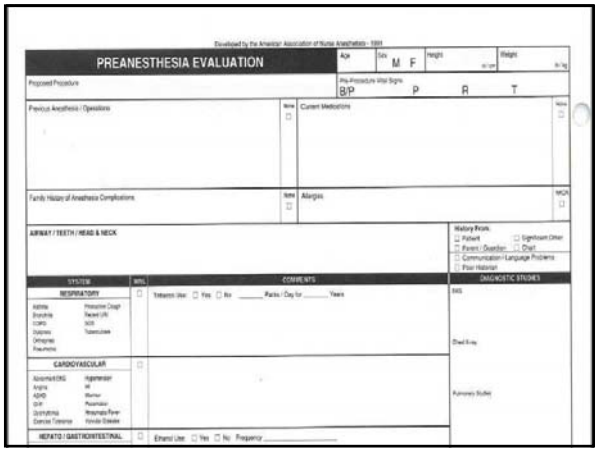
PREANESTHESIA EVALUATION

Age

Sex M F

Height

Weight

Proposed Procedure

Pre-Procedure Vital Signs

B/P P R T

Previous Anesthesia / Operations

Current Medications

Family History of Anesthesia Complications

Allergies

AIRWAY / TEETH / HEAD & NECK

History From:
Patient
Parent / Guardian
Chart
Communication / Language Problems
Poor Historian

SYSTEM | WNL | COMMENTS | DIAGNOSTIC STUDIES

RESPIRATORY

CARDIOVASCULAR

HEPATO / GASTROINTESTINAL

EKG

Chest X-ray

Pulmonary Studies

ASA Physical Status Classification System

- ASA PS I – normal healthy patient
- ASA PS II – patient with mild systemic disease
- ASA PS III – patient with severe systemic disease
- ASA PS IV – patient with severe systemic disease that is a constant threat to life
- ASA PS V – moribund patient who is not expected to survive without the operation
- ASA PS VI – declared brain-dead patient whose organs are being removed for donor purposes

100

Survey Procedure Pre-anesthesia Evaluation

- Surveyor to review sample of inpatient and outpatient records who had anesthesia
- Make sure pre-anesthesia evaluation done and by one qualified to deliver anesthesia
- Determine the pre-anesthesia evaluation had all the required elements
- Make sure done within 48 hours before first does of medication given for purposes of inducing anesthesia for the surgery or procedure
- ASA and AANA has pre-anesthesia standards that hospitals should be familiar with

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ASA Guideline Pre-Anesthesia

- Preanesthesia Evaluation [1]
  - Patient interview to assess Medical history, Anesthetic history, Medication history
- Appropriate physical examination
- Review of objective diagnostic data (e.g., laboratory, ECG, X-ray)
- Assignment of ASA physical status
- Formulation of the anesthetic plan and discussion of the risks and benefits of the plan with the patient or the patient's legal representative

1 www.asahq.org/publicationsAndServices/standards/03.pdf American Society of Anesthesiologist

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STANDARDS FOR BASIC ANESTHETIC MONITORING

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010 with an effective date of July 1, 2011)

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual† monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

1. STANDARD I

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

1.1 Objective –

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$ETCO_2$ for Moderate and Deep Sedation ASA

3.2.4 During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

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ASA Practice Advisory Preanesthesia Evaluation

http://asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx

SPECIAL ARTICLE

Practice Advisory for Preanesthesia Evaluation

A Report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care where scientific evidence is insufficient to develop an evidence-based model. Practice advisories provide a synthesis of opinion from experts, open forums, and other public sources. Practice advisories report the current state of scientific literature, but are not supported by literature to the same degree as standards or guidelines due to the lack of sufficient numbers of adequately controlled studies.

Advisories are not intended as guidelines, standards, or absolute requirements. The use of practice advisories cannot guarantee any specific outcome. They may be adopted, modified, or rejected according to clinical needs and constraints. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Definition of Preanesthesia Evaluation

the patient's medical records, interview, physical examination, and findings from medical tests and evaluations. As part of the preanesthesia evaluation process, the anesthesiologist may choose to consult with other healthcare professionals to obtain information or services that are relevant to perioperative anesthetic care. Preoperative tests, as a component of the preanesthesia evaluation, may be indicated for various purposes, including but not limited to (1) discovery or identification of a disease or disorder that may affect perioperative anesthetic care, (2) verification or assessment of an already known disease, disorder, medical or alternative therapy that may affect perioperative anesthetic care, and (3) formulation of specific plans and alternatives for perioperative anesthetic care. For this Advisory, *perioperative* refers to the care surrounding operations and procedures.

The assessments made in the process of a preanesthesia evaluation may be used to educate the patient, organize resources for perioperative care, and formulate

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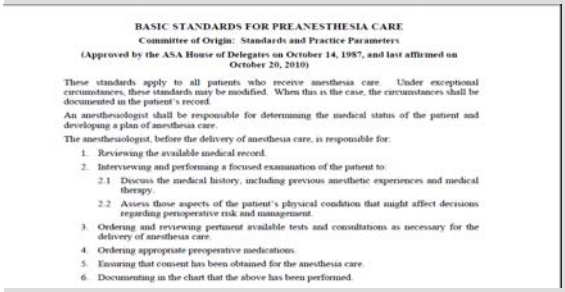
ASA Standard on Pre-anesthesia Care



BASIC STANDARDS FOR PREANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 14, 1987, and last affirmed on October 20, 2010)

These standards apply to all patients who receive anesthesia care. Under exceptional circumstances, these standards may be modified. When this is the case, the circumstances shall be documented in the patient's record.

An anesthesiologist shall be responsible for determining the medical status of the patient and developing a plan of anesthesia care.

The anesthesiologist, before the delivery of anesthesia care, is responsible for:

1. Reviewing the available medical record.
2. Interviewing and performing a focused examination of the patient to:
   - 2.1 Discuss the medical history, including previous anesthetic experiences and medical therapy.
   - 2.2 Assess those aspects of the patient's physical condition that might affect decisions regarding perioperative risk and management.
3. Ordering and reviewing pertinent available tests and consultations as necessary for the delivery of anesthesia care.
4. Ordering appropriate preoperative medications.
5. Ensuring that consent has been obtained for the anesthesia care.
6. Documenting in the chart that the above has been performed.

http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

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Intra-operative Anesthesia Record 1004

- Need policies related to the intra-operative anesthesia record
- Need intra-operative anesthesia record for patients who have general, regional, deep sedation or MAC
- Still need monitoring of moderate sedation before, during, and after but the monitoring required by this section does not apply to that
- See the TJC standards on this

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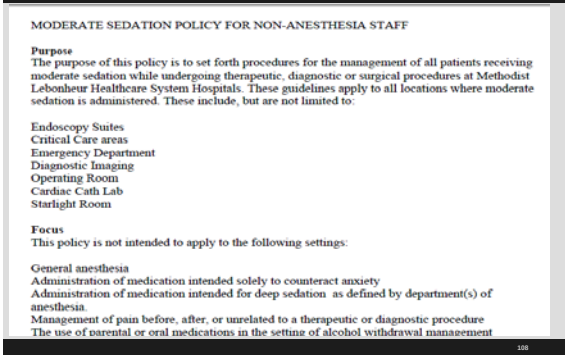
So What's In Your Policy?



MODERATE SEDATION POLICY FOR NON-ANESTHESIA STAFF

Purpose

The purpose of this policy is to set forth procedures for the management of all patients receiving moderate sedation while undergoing therapeutic, diagnostic or surgical procedures at Methodist Lebonheur Healthcare System Hospitals. These guidelines apply to all locations where moderate sedation is administered. These include, but are not limited to:

Endoscopy Suites
Critical Care areas
Emergency Department
Diagnostic Imaging
Operating Room
Cardiac Cath Lab
Starlight Room

Focus

This policy is not intended to apply to the following settings:

General anesthesia
Administration of medication intended solely to counteract anxiety
Administration of medication intended for deep sedation as defined by department(s) of anesthesia.
Management of pain before, after, or unrelated to a therapeutic or diagnostic procedure
The use of parental or oral medications in the setting of alcohol withdrawal management

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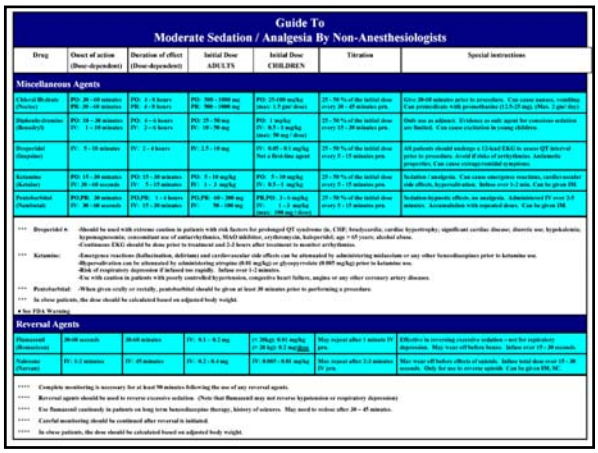


Guide To
Moderate Sedation / Analgesia By Non-Anesthesiologists

Drug	Onset of action (Dose-dependent)	Duration of effect (Dose-dependent)	Initial Dose ADULTS	Initial Dose CHILDREN	Titration	Special instructions
Miscellaneous Agents						
Chloral Hydrate (Noctec)	PO: 20 - 60 minutes PR: 20 - 60 minutes	PO: 4 - 8 hours PR: 4 - 8 hours	PO: 500 - 1000 mg PR: 500 - 1000 mg	PO: 25-100 mg/kg (max: 1.5 gm/ dose)	25 - 50 % of the initial dose every 20 - 45 minutes prn	Give 30-60 minutes prior to procedure. Can cause nausea, vomiting. Can primedicate with promethazine (12.5-25 mg). (Max. 2 gm/ day)
Diphenhydramine (Benadryl)	PO: 30 - 60 minutes IV: 1 - 10 minutes	PO: 4 - 6 hours IV: 2 - 4 hours	PO: 25 - 50 mg IV: 10 - 50 mg	PO: 1 mg/kg IV: 0.5 - 1 mg/kg (max: 50 mg / dose)	25 - 50 % of the initial dose every 15 - 20 minutes prn	Only use as adjunct. Evidence as safe agent for conscious sedation are limited. Can cause excitation in young children.
Droperidol (Inapsine)	IV: 5 - 10 minutes	IV: 2 - 4 hours	IV: 2.5 - 10 mg	IV: 0.05 - 0.1 mg/kg Not a first-line agent	25 - 50 % of the initial dose every 5 - 15 minutes prn	All patients should undergo a 12-lead EKG to assess QT interval prior to procedure. Avoid if risks of arrhythmias. Antiemetic properties. Can cause extrapyramidal symptoms.
Ketamine (Ketalar)	PO: 15 - 20 minutes IV: 20 - 60 seconds	PO: 15 - 20 minutes IV: 5 - 15 minutes	PO: 5 - 10 mg/kg IV: 1 - 2 mg/kg	PO: 5 - 10 mg/kg IV: 0.5 - 1 mg/kg	25 - 50 % of the initial dose every 5 - 15 minutes prn	Sedation / analgesia. Can cause emergence reactions, cardiovascular side effects, hypersalivation. Inflow over 1-2 min. Can be given IM.
Promethazine (Phenhergan)	PO/PR: 20 minutes IV: 30 - 60 seconds	PO/PR: 1 - 4 hours IV: 15 - 20 minutes	PO/PR: 60 - 200 mg IV: 50 - 100 mg	PR/PO: 1 - 1 mg/kg IV: 1 - 2 mg/kg (max: 100 mg / dose)	25 - 50 % of the initial dose every 5 - 15 minutes prn	Sedation-hypnotic effects, no analgesia. Administered IV over 2-5 minutes. Accumulation with repeated doses. Can be given IM.

*** Droperidol x: Should be used with extreme caution in patients with risk factors for prolonged QT syndrome (ie, CHF, bradycardia, cardiac hypertrophy, significant cardiac disease, diuretic use, hypokalemia, hypomagnesemia, concomitant use of antiarrhythmics, MAO inhibitor, erythromycin, haloperidol, age >45 years, alcohol abuse. 4 continuous EKG should be done prior to treatment and 2-3 hours after treatment to monitor arrhythmias.

*** Ketamine: -Emergence reactions (hallucination, delirium) and cardiovascular side effects can be attenuated by administering midazolam or any other benzodiazepines prior to ketamine use. -Hypersalivation can be attenuated by administering atropine (0.01 mg/kg) or glycopyrrolate (0.005 mg/kg) prior to ketamine use. -Risk of respiratory depression if infused too rapidly. Inflow over 1-2 minutes. -Use with caution in patients with poorly controlled hypertension, congestive heart failure, angina or any other coronary artery disease.

*** Promethazine: -When given orally or rectally, promethazine should be given at least 30 minutes prior to performing a procedure.

*** In obese patients, the dose should be calculated based on adjusted body weight.

• See FDA Warning

Reversal Agents						
Flumazenil (Romazicon)	30-60 seconds	30-60 minutes	IV: 0.1 - 0.2 mg	IV 20kg): 0.01 mg/kg IV 20 kg): 0.2 mg/kg	May repeat after 1 minute IV prn	Effective in reversing excessive sedation - not for respiratory depression. May wear off before benzo. Inflow over 15 - 30 seconds.
Naloxone (Narcan)	IV: 1-2 minutes	IV: 45 minutes	IV: 0.2 - 0.4 mg	IV: 0.005 - 0.01 mg/kg	May repeat after 2-3 minutes IV prn	May wear off before effects of opioids. Inflow total dose over 15 - 30 seconds. Only for use to reverse opioids. Can be given SQ, IM.

**** Complete monitoring is necessary for at least 90 minutes following the use of any reversal agents.

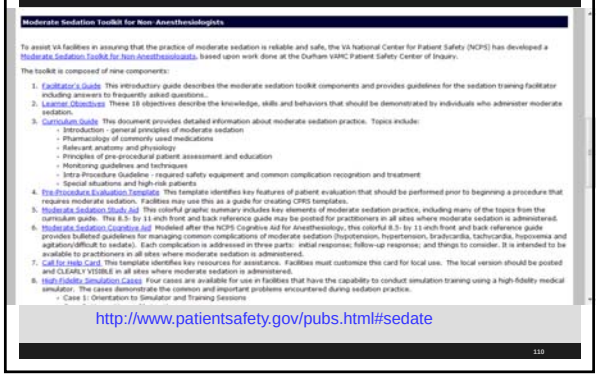
**** Reversal agents should be used to reverse excessive sedation. (Note that flumazenil may not reverse hypotension or respiratory depression)

**** Use flumazenil cautiously in patients on long term benzodiazepine therapy, history of seizures. May need to redose after 20 – 45 minutes.

**** Careful monitoring should be continued after reversal is initiated.

**** In obese patients, the dose should be calculated based on adjusted body weight.

Moderate Sedation Toolkit



Moderate Sedation Toolkit for Non-Anesthesiologists

To assist VA facilities in assuring that the practice of moderate sedation is reliable and safe, the VA National Center for Patient Safety (NCPS) has developed a Moderate Sedation Toolkit for Non-Anesthesiologists, based upon work done at the Durham VAMC Patient Safety Center of Inquiry.

The toolkit is composed of nine components:

1. Facilitator's Guide This introductory guide describes the moderate sedation toolkit components and provides guidelines for the sedation training facilitator including answers to frequently asked questions.
2. Learner Objectives These 18 objectives describe the knowledge, skills and behaviors that should be demonstrated by individuals who administer moderate sedation.
3. Curriculum Guide This document provides detailed information about moderate sedation practice. Topics include:
   - Introduction - general principles of moderate sedation
   - Pharmacology of commonly used medications
   - Relevant anatomy and physiology
   - Principles of pre-procedural patient assessment and education
   - Monitoring guidelines and techniques
   - Intra-Procedure Guideline - required safety equipment and common complication recognition and treatment
   - Special situations and high-risk patients
4. Pre-Procedure Evaluation Template This template identifies key features of patient evaluation that should be performed prior to beginning a procedure that requires moderate sedation. Facilities may use this as a guide for creating CPRS templates.
5. Moderate Sedation Study Aid This colorful graphic summary includes key elements of moderate sedation practice, including many of the topics from the curriculum guide. This 8.5- by 11-inch front and back reference guide may be posted for practitioners in all sites where moderate sedation is administered.
6. Moderate Sedation Cognitive Aid Modeled after the NCPS Cognitive Aid for Anesthesiology, this colorful 8.5- by 11-inch front and back reference guide provides bulleted guidelines for managing common complications of moderate sedation (hypotension, hypertension, bradycardia, tachycardia, hypoxemia and agitation/difficult to sedate). Each complication is addressed in three parts: initial response; follow-up response; and things to consider. It is intended to be available to practitioners in all sites where moderate sedation is administered.
7. Call for Help Card This template identifies key resources for assistance. Facilities must customize this card for local use. The local version should be posted and CLEARLY VISIBLE in all sites where moderate sedation is administered.
8. High-Fidelity Simulation Cases Four cases are available for use in facilities that have the capability to conduct simulation training using a high-fidelity medical simulator. The cases demonstrate the common and important problems encountered during sedation practice.
   - Case 1: Orientation to Simulator and Training Sessions

http://www.patientsafety.gov/pubs.html#sedate

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Intra-operative Anesthesia Record 1004

- Intra-operative Record must contain the following:
  - Include name and hospital id number
  - Name of practitioner who administer anesthesia
  - Techniques used and patient position, including insertion of any intravascular or airway devices
  - Name, dosage, route and time of drugs
  - Name and amount of IV fluids

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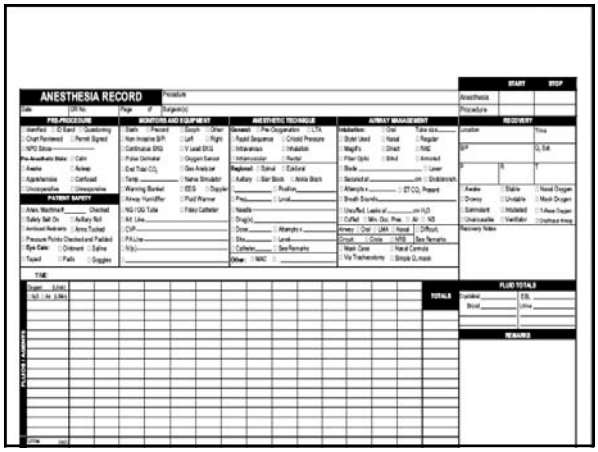
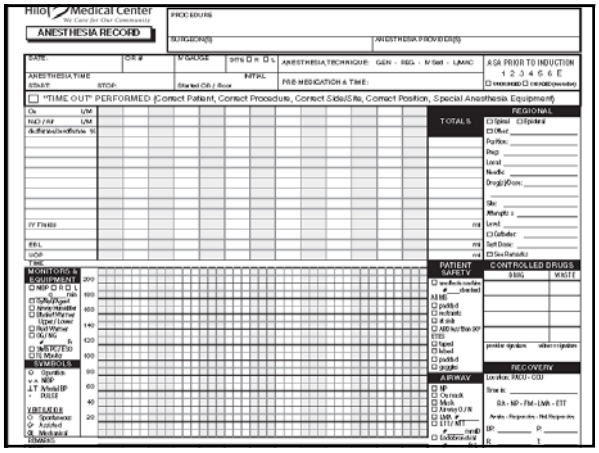
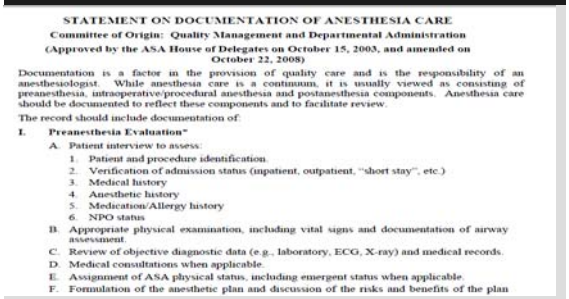
Intra-operative Anesthesia Record 1004

- Intra-operative Record must contain the following (continued):
  - Blood/blood products
  - Oxygenation and ventilation parameters
  - Time based documentation of continuous vital signs
  - Complications, adverse reactions, problems during anesthesia with symptom, VS, treatment rendered and response to treatment





ASA Document Anesthesia Care



STATEMENT ON DOCUMENTATION OF ANESTHESIA CARE

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 15, 2003, and amended on October 22, 2008)

Documentation is a factor in the provision of quality care and is the responsibility of an anesthesiologist. While anesthesia care is a continuum, it is usually viewed as consisting of preanesthesia, intraoperative/procedural anesthesia and postanesthesia components. Anesthesia care should be documented to reflect these components and to facilitate review.

The record should include documentation of:

I. Preanesthesia Evaluation"

A. Patient interview to assess:
1. Patient and procedure identification.
2. Verification of admission status (inpatient, outpatient, "short stay", etc.)
3. Medical history
4. Anesthetic history
5. Medication/Allergy history
6. NPO status

B. Appropriate physical examination, including vital signs and documentation of airway assessment.

C. Review of objective diagnostic data (e.g., laboratory, ECG, X-ray) and medical records.

D. Medical consultations when applicable.

E. Assignment of ASA physical status, including emergent status when applicable.

F. Formulation of the anesthetic plan and discussion of the risks and benefits of the plan

http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

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Post-Anesthesia Evaluation 1005

- Must have policies in place to ensure compliance with the post-anesthesia evaluation requirements
- Post-anesthesia evaluation must be done by some one who is qualified to give anesthesia
  - 5 who are qualified to give as previously mentioned
  - Can not delegate it to a RN, PA, or NP
- Must be done no later than 48 hours after the surgery or procedure requiring anesthesia services

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Post-Anesthesia Evaluation 1005

- Must be completed as required by hospital policies and procedures
- Must be completed as required by any state specific laws
  - State law can be more stringent but not less stringent so if state wants to require it to be done in 24 instead of 48 hours you must comply
- P&Ps must be approved by the MS
- P&Ps must reflect current standards of care

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Post Anesthesia Evaluation 1005

- Document in chart within 48 hours for patients receiving anesthesia services (general, regional, deep sedation, MAC)
- For inpatients and outpatients now
  - So may have to call some outpatients if not seen before they left the hospital
  - Note different for CAH hospitals under their manual under tag 322 (perform before patient leaves the hospital)
- Does not have to be done by the same person who administered the anesthesia

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Post Anesthesia Evaluation 1005

- Has to be done only by anesthesia person (CRNA, AA, anesthesiologist) or qualified doctor, dentist, podiatrist, or oral surgeon
- 48 hours starts at time patient moved into PACU or designated recovery area (SICU etc.)
- 48 hour is an outside parameter
- Individual risk factors may dictate that the evaluation be completed and documented sooner than 48 hours
  - This should be addressed by hospital P&P

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Post Anesthesia Evaluation 1005

- Evaluation can not generally be done at point of movement to the recovery area since patient not recovered from anesthesia
  - Patient must be sufficiently recovered so as to participate in the evaluation e.g. answer questions, perform simple tasks etc.

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Post Anesthesia Evaluation

- For same day surgeries may be done after discharge if allowed by P&P and state law
- If the patient is still intubated and in the ICU still need to do within the 48 hours
  - Would just document that the patient is unable to participate
  - If patient requires long acting anesthesia that would last beyond the 48 hours would just document this and note that full recovery from regional anesthesia has not occurred

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Post-Anesthesia Assessment to Include 1005

- Respiratory function with respiratory rate, airway patency and oxygen saturation
- CV function including pulse rate and BP
- Mental status, temperature
- Pain
- Nausea and vomiting
- Post-operative hydration
  - Consider having a form to capture these requirements

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Post-Anesthesia Survey Procedure

- Surveyor is review medical records for patients having anesthesia and make sure post-anesthesia evaluation is in the chart
- Surveyor to make sure done by practitioner who is qualified to give anesthesia
- Surveyor to make sure all postanesthesia evaluations are done within 48 hours
- Surveyor to make sure all the required elements are documented for the postanesthesia evaluation

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Post Anesthesia ASA Guidelines

- Patient evaluation on admission and discharge from the postanesthesia care unit
- A time-based record of vital signs and level of consciousness
- A time-based record of drugs administered, their dosage and route of administration
- Type and amounts of intravenous fluids administered, including blood and blood products
- Any unusual events including postanesthesia or post procedural complications
- Post-anesthesia visits

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STANDARDS FOR POSTANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 27, 2004, and last amended on October 21, 2009)

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.

STANDARD I

ALL PATIENTS WHO HAVE RECEIVED GENERAL ANESTHESIA, REGIONAL ANESTHESIA OR MONITORED ANESTHESIA CARE SHALL RECEIVE APPROPRIATE POSTANESTHESIA MANAGEMENT.[1]

1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (for example, a Surgical Intensive Care Unit) shall be available to receive patients after anesthesia care. All patients who receive anesthesia care shall be admitted to the PACU or its equivalent **except** by specific order of the anesthesiologist responsible for the patient's care.
2. The medical aspects of care in the PACU (or equivalent area) shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.
3. The design, equipment and staffing of the PACU shall meet requirements of the facility's accrediting and licensing bodies.

STANDARD II

A PATIENT TRANSPORTED TO THE PACU SHALL BE ACCOMPANIED BY A MEMBER OF THE ANESTHESIA CARE TEAM WHO IS KNOWLEDGEABLE ABOUT THE PATIENT'S CONDITION. THE PATIENT SHALL BE CONTINUALLY EVALUATED AND TREATED DURING TRANSPORT WITH MONITORING AND SUPPORT APPROPRIATE TO THE PATIENT'S CONDITION.

STANDARD III

UPON ARRIVAL IN THE PACU, THE PATIENT SHALL BE RE-EVALUATED AND A VERBAL REPORT PROVIDED TO THE RESPONSIBLE PACU NURSE BY THE MEMBER

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ASA Standard Postanesthesia Care

STANDARDS FOR POSTANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 27, 2004, and last amended on October 21, 2009)

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.

STANDARD I

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http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

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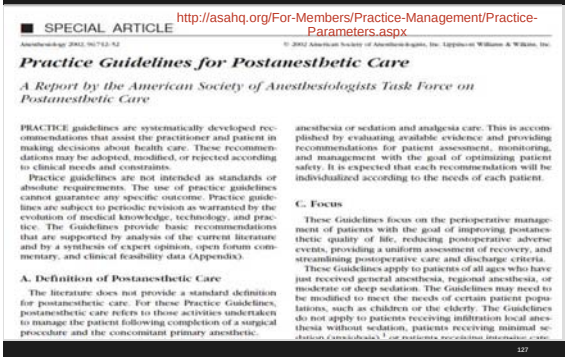
ASA Practice Guideline Postanesthesia Care

http://asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx



SPECIAL ARTICLE

Practice Guidelines for Postanesthetic Care

A Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care

PRACTICE 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.

Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice. The Guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data (Appendix).

A. Definition of Postanesthetic Care

The literature does not provide a standard definition for postanesthetic care. For these Practice Guidelines, postanesthetic care refers to those activities undertaken to manage the patient following completion of a surgical procedure and the concomitant primary anesthetic anesthesia or sedation and analgesia care. This is accomplished by evaluating available evidence and providing recommendations for patient assessment, monitoring, and management with the goal of optimizing patient safety. It is expected that each recommendation will be individualized according to the needs of each patient.

C. Focus

These Guidelines focus on the perioperative management of patients with the goal of improving postanesthetic quality of life, reducing postoperative adverse events, providing a uniform assessment of recovery, and streamlining postoperative care and discharge criteria.

These Guidelines apply to patients of all ages who have just received general anesthesia, regional anesthesia, or moderate or deep sedation. The Guidelines may need to be modified to meet the needs of certain patient populations, such as children or the elderly. The Guidelines do not apply to patients receiving infiltration local anesthesia without sedation, patients receiving minimal se-

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Six FAQs

- How can the same drugs be used in the OR for anesthesia but in the ED for a sedative?
- What nationally recognized guidelines are available for hospitals to use to develop their P&Ps?
- What is the appropriate training for a sedation nurse?
- Why is there a particular mention in the interpretive guidelines on ED sedation policies?
- Can hospital adopt a P&P that all anesthesia agents in lower doses can be used for sedation (NO!)

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FAQ 1 Drugs Used

The following questions and answers are provided to facilitate understanding of the revised guidance:

Q1: How can the same drug be used at the same facility for general anesthesia in the operating room and for a sedative in the emergency department or a procedure room?

A1: The physiological result in terms of level of sedation for a particular medication may vary based on dosage, route and timing of administration, the metabolism and interaction with other medications, the clinical status and body habitus of the patient, etc. However, there is neither a bright line nor predictability about when a patient will inadvertently convert from moderate to deep sedation, or how much medication will bring about the desired sedation state. In addition, for some medications there is no antidote that can quickly reverse its effects; rescue of an overly-sedated patient requires very specific skills in airway management and ventilation. For this reason the IG continues to require that hospitals ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than originally intended.

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Question 2 National Standards of Care

Q2: What nationally recognized guidelines are available for hospitals to use to develop their policies concerning what is anesthesia and what is analgesia and which procedures need which? What does "nationally recognized guidelines" mean?

A2: CMS' expectation is that such guidelines are issued by a national organization that has appropriate expertise and which has used consensus-setting process of professionals with appropriate expertise in developing its guidelines. We recognize that such organizations may not always fully agree with each other. Examples of organizations with guidelines related to anesthesia administration include, but not limited to, the following:

- The American Society of Anesthesiologists (ASA)
  - Practice Guidelines on Sedation and Analgesia by Non-anesthesiologists and the ASA House of Delegates statement on the use of propofol are available at http://www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx
- The American College of Emergency Physicians (ACEP)
  - Clinical Policies Subcommittee, which included members of ACEP and the Emergency Nurses Association (ENA) published their "Clinical policy on

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Questions 3 and 3 ED and Sedation Nurse

Q3: What is the appropriate training for a "sedation" nurse?

A3: Currently there is no Medicare definition of a "sedation nurse," nor does there appear to be any uniformly accepted training for a sedation nurse. Some states specifically address RN-administered sedation in their professional licensure laws and regulations. It is possible that national organizations producing anesthesia guidelines may develop guidelines/recommendations in this area in the future.

Q4: Why is there a particular mention in the IG on the emergency department's (ED's) sedation policies?

A4: The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality. In addition, emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is

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Question 5 Under One Individual

Q5: The regulations and IG state that hospital anesthesia services be under the direction of one individual. How can hospitals ensure that the policies and procedures that define the various uses of analgesia and anesthesia are not too narrow (or broad) or based on the opinions of one individual?

A5: In the IG, hospitals are encouraged to develop the anesthesia services policies in collaboration with other hospital disciplines, such as surgery, pharmacy, nursing, safety experts, etc. A hospital may choose to require medical staff review and approval of the anesthesia policies. These collaborative approaches are not, however, a regulatory requirement. A hospital may therefore allow the director to develop the policies alone. However, as in all cases, the hospital's governing body is ultimately responsible to assure that the policies adopted meet the regulatory requirements.

Q6: Is it acceptable if a hospital adopts a policy stating that all anesthetic agents in lower doses can be used for sedation and therefore no medications qualify as anesthesia, and thus there is no need for them to be administered by anesthesia professionals? Is this acceptable?

A6: We are not aware of any such nationally recognized guidelines at this time, nor do we think it likely that an organization would adopt a broad guideline stating that there are no medications that ever qualify as anesthesia.

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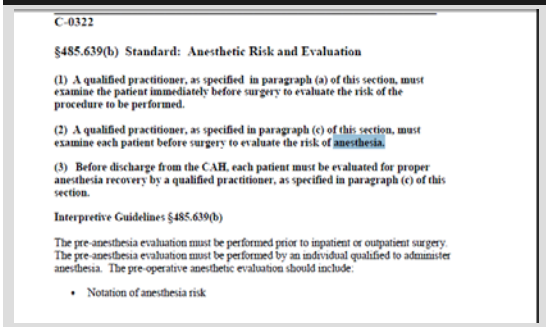
Anesthesia Standard CAH



C-0322

§485.639(b) Standard: Anesthetic Risk and Evaluation

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk

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CAH Hospitals

- Current CAH manual
- Anesthesia standard starts at tag C-0322 and see 323
  - Most of the sections are the same
- The PPS hospital anesthesia standards provide more detailed information on how this section will be surveyed
  - Will cover the differences for CAH hospitals
- Much shorter section
  - Does not mention CRNA going to OB unit to put in epidural but most likely is treated the same

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CAH Pre-anesthesia Assessment C-322

- Must be done by qualified practitioner
  - Example would include CRNA and anesthesiologist
- Includes what must be in the preanesthesia assessment
  - Notation of anesthesia risk
  - Anesthesia, drug and allergy history
  - Any potential anesthesia problems identified
  - Patient's condition prior to induction of anesthesia

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Post Anesthesia Assessment CAH 322

- Cardiopulmonary status
- Level of consciousness
- Any follow-up care and/or observations and
- Any complications occurring during post-anesthesia recovery
- States that the postanesthesia follow up report must be written prior to discharge from anesthesia services

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The End! Questions?

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CPHRM , CCMSCP
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TJC standards follow

ASGE, ACEP (ED), ENA

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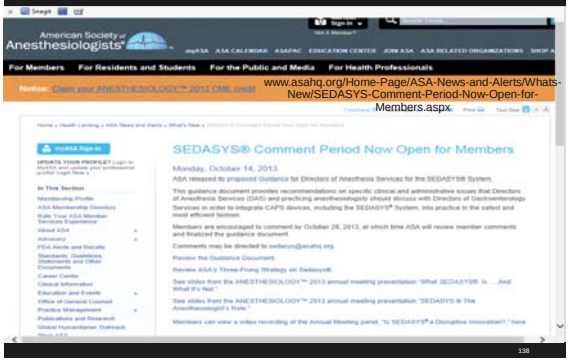
Computer Assisted Personalized Sedation CAPS



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SEDASYS

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Computer Assisted Personalized Sedation

- FDA has granted Premarket Approval of SEDASYS and expected others will follow in the marketplace
- Designed to achieve minimal to moderate sedation
- Good information on ASA website
- CAPS devices references CMS hospital CoP standards that all anesthesia services must be provided in an organized manner
- Should collect data for PI and monitor outcomes so make PI department aware of this

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AQI Quality Metrics for Procedural Sedation

Anesthesia Quality Institute

www.aqihq.org/qualitymeasurementtools.aspx

Quality Metrics for Procedural Sedation

AQI consensus recommendations for the Director of Anesthesia Services charged with initiating a quality management program in procedural sedation. Data must be gathered each month from each unit where patients receive sedation. Data gathering should be modified as necessary to fit the information technology available and the patient population served.

Core Elements

Volume Metrics
- Type and number of procedures performed
- Number of patients receiving light or moderate sedation
  - Number receiving sedation via Computer-Assisted Personalized Sedation (CAPS)
- Number of patients receiving deep sedation
- Number of patients cared for by an anesthesia team

Outcomes
- Cases completed as planned, without complication, *versus:*
- Cases cancelled due to patient discomfort or anxiety
- Cases with unplanned escalation in the continuum of sedation
- Patients receiving rescue medication: flumazenil or naloxone
- Unplanned respiratory support required in light or moderate sedation cases
  - Placement of nasal trumpet or oral airway
  - Placement of supraglottic airway (e.g. LMA) or endotracheal tube
  - Assisted ventilation with bag-valve-mask
  - Oxygen saturation < 85% for greater than 3 minutes
- Patients experiencing a serious adverse event (e.g. perforation, anaphylaxis, cardiac arrest)

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Computer Assisted Personalized Sedation

- Device label indicates patient gets single dose of Fentanyl (25 to 100 mg) 3 minutes before
- Then IV 1% Profofol (10mg/ml)
- For patients over 18 having colonoscopy and EGD procedures (esphagogastroduodenoscopy)
- Anesthesia professional must be immediately available for assistance or consult if needed
- Code team or rapid response team
- GI doctor should consult anesthesia if concerns about sedation

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Computer Assisted Personalized Sedation

- Label states must have training in the management of cardio-respiratory effects of Propofol
- Physician and staff should be trained
- ASA (proposed) recommends training in pharmacology of propofol, identification of high risk patients, recognition of progressive levels of sedation, actions to return patient to intended level, use capnography, pulse ox and manage airways
- Staff should be familiar with the FDA recommendations and training program developed and submitted to them

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Have a Policy and Training

GUIDANCE FOR DIRECTORS OF ANESTHESIA SERVICE FOR COMPUTER-ASSISTED PERSONALIZED SEDATION (CAPS) DEVICES

Committee of Origin: Ad Hoc Committee on SEDASYS®[1]

On May 3, 2013, Ethicon Endo-Surgery, Inc., a subsidiary of Johnson & Johnson (J&J), announced that the Food and Drug Administration (FDA) granted Premarket Approval for the SEDASYS® System, a computer-assisted personalized sedation system designed to achieve and maintain minimal-to-moderate sedation. The SEDASYS® System is expected to be introduced on a limited basis beginning in 2014, and is likely to be followed in the marketplace by other similar CAPS devices.

Since the May 2013 announcement, the American Society of Anesthesiologists (ASA) established a three-pronged strategy to understand this topic and educate members: 1) ASA established an Ad Hoc Committee on the SEDASYS® System that developed this Guidance and is leading efforts to enhance the safety of the device; 2) ASA is developing a relationship with J&J that will allow us to work together to safely and efficiently integrate the SEDASYS® System into practice; and 3) members of the Ad Hoc Committee on SEDASYS® and ASA staff met with key officials from the FDA's Center for Devices and Radiological Health to discuss ASA's questions and explore an enhanced role for ASA with the FDA relative to this device and other future devices. Additional information on ASA's three-pronged strategy on the SEDASYS® System is available here: http://www.asahq.org/Home-Page/ASA-News-and-Alerts/Whats-New/ASA-launches-three-prong-strategy-in-response-to-Premarket-Approval-for-SEDASYS.aspx

This guidance document will provide recommendations on specific clinical and administrative issues that Directors of Anesthesia Services (DAS) and practicing anesthesiologists should discuss with Directors of Gastroenterology Services in order to integrate CAPS devices, including the SEDASYS® System, into practice in the safest and most efficient fashion.

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FDA Approval

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SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Computer-Assisted Personalized Sedation System

Device Trade Name: SEDASYS® Computer-Assisted Personalized Sedation System

Device Procode: PDR

Applicant's Name and Address: Ethicon Endo-Surgery (EES), Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Date of Panel Recommendation: May 28, 2009

Premarket Approval Application (PMA) Number: P080009

Date of FDA Notice of Approval: May 3, 2013

Expedited: Granted expedited review status on April 9, 2008 because the SEDASYS System may offer a viable alternative to the current standard of practice for colonoscopy or esophagogastroduodenoscopy (EGD) procedures.

II. INDICATIONS FOR USE

The SEDASYS System is indicated for the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of minimal to moderate sedation, as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients ≥ 18 years old undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures.

III. CONTRAINDICATIONS

The SEDASYS System is contraindicated in the following:

- Patients with a known hypersensitivity to 1% propofol injectable emulsion or its components.
- Patients with allergies to eggs, egg products, soybeans or soy products.
- Patients with a known hypersensitivity to fentanyl.
- Pregnant or lactating women.
- Delivery of any drug other than 1% propofol injectable emulsion.
- Patients with a full stomach.

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Epidural or Spinal for Pain Relief

- Bucket one analgesia or pain
  - CMS removes language that says administration of epidural or spinal during labor and delivery is not subject to the anesthesia standard
- Need policy on who can do analgesia such as PA, NP, or RN
  - PA, physician or NP may give local with Lidocaine to suture in the ED
  - RN may give Valium 2.5 mg to patient before MRI
  - RN may help with moderate sedation in the ED or GI lab

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CDC Requirements

- Any CRNA or anesthesiologist who puts in an epidural or spinal should remember the CDC standard
- The CDC requires that a mask be worn
- There were five women who had an epidural for pain relief and the anesthesiologist did not wear a mask
- All became septic and one dies from strept salivarius
- CDC issues a notice in MMWR

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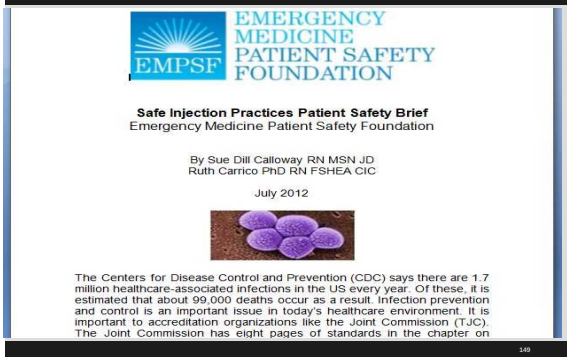
Free at www.empsf.org



EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

By Sue Dill Calloway RN MSN JD
Ruth Carrico PhD RN FSHEA CIC

July 2012

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention and control is an important issue in today's healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on

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Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (*MMWR*)

www.cdc.gov/mmwr/preview/mmwrhtml/mm5903a1.htm

Bacterial Meningitis After Intrapartum Spinal Anesthesia --- New York and Ohio, 2008--2009

Weekly

January 29, 2010 / 59(03);65-69

In June 2007, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended for the first time that surgical masks be worn by spinal procedure operators to prevent infections associated with these procedures (1). HICPAC made the recommendation in response to several reports of meningitis following myelography procedures. In September 2008, three bacterial meningitis cases in postpartum women were reported to the New York State Department of Health (NYSDOH); in May 2009, two similar cases were reported to the Ohio Department of Health. All five women had received intrapartum spinal anesthesia. Four were confirmed to have *Streptococcus salivarius* meningitis, and one woman subsequently died. This report summarizes the investigations of these five cases, which determined that the New York cases were associated with one anesthesiologist and the Ohio cases were associated with a second anesthesiologist. In Ohio, the anesthesiologist did not wear a mask; wearing a mask might have prevented the infections. The findings underscore the need to follow established infection-control recommendations during spinal procedures, including the use of a mask and adherence to aseptic technique.

Case Reports

New York. In September 2008, a healthy woman aged 24 years (patient A) was admitted in active labor to a New York City hospital. She received combined spinal-epidural anesthesia from anesthesiologist A, and delivered a healthy baby. Approximately 22 hours after receiving anesthesia, patient A experienced headache, back pain, rigors, nausea, vomiting, and disorientation.

Within 1 hour of patient A's admission, a second healthy woman aged 31 years (patient B) was admitted to the same hospital in

Injection Safety CDC

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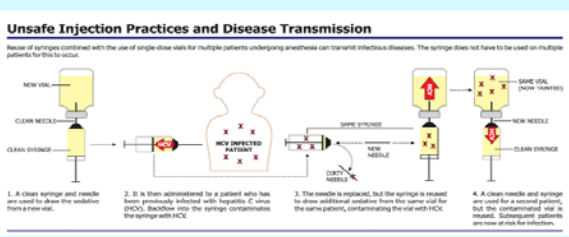
Unsafe Injection Practices and Disease Transmission



Source: www.southernnevadahealthdistrict.org

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II. Injection Practices (injectable medications, saline, other infusates) **Additional Instructions:** **Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).**		
Practices to be Assessed	**Was practice performed?**	**Manner of confirmation**
A. Needles are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
B. Syringes are used for only one patient	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
C. Medication vials are always entered with a new needle	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
D. Medication vials are always entered with a new syringe	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both
E. Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength, and expiration date or time Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs	1 Yes 2 No 3 N/A	4Observation 5Interview 6Both

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EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

www.empsf.org

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Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012

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Infection prevention and control is also important to the Centers for

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Injection Practices & Sharps Safety

- CMS Worksheet on IC has section on injection practices and sharps safety
- This includes medications, saline, and other infusates
- Injections are given and sharps safety is managed in a manner consistent with IC P&P
- CDC has standards on self injection practices
- Injections are prepared using aseptic technique
- One needle, one syringe for every patient and includes insulin pens (CMS issues memo May 18, 2012)

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Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

Elements to be assessed		Manner of Assessment Code (check all that apply) & Surveyor Notes		Manner of Assessment Code (check all that apply) & Surveyor Notes
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:				
2. B.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. B.2 Needles are used for only one patient.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	☐ Yes ○ No ○ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Interview = 1 Observation = 2 Infection Control Document Review = 3 Medical Record Review = 4 Other Document Review = 5

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Page 11 of 42

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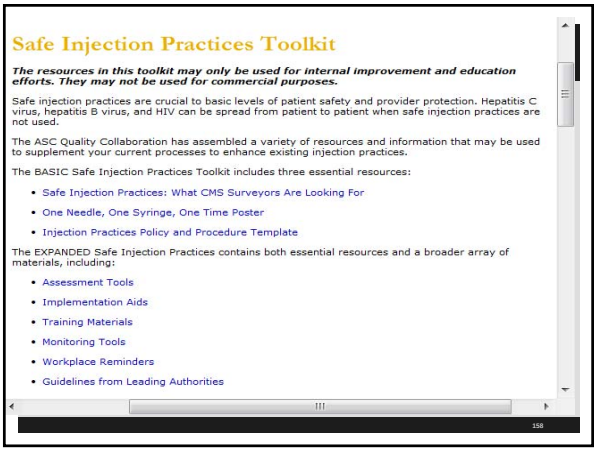
Safe Injections Practices Toolkit

http://ascquality.org/advancing_asc_quality.cfm



Standards of Practice

- Standards of care and practice follow including:
- ASA
- ACEP
- ENA
- AANA
- ASGE
- ACS

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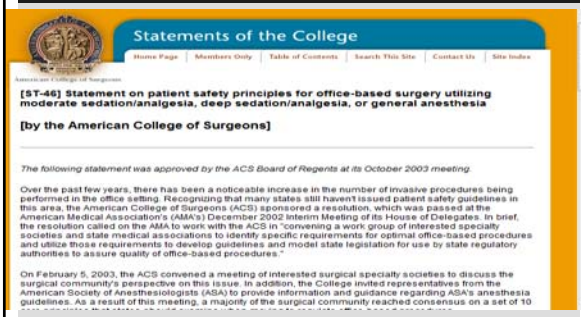
AGS Office Based Deep Sedation, General etc



Statements of the College

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[ST-46] Statement on patient safety principles for office-based surgery utilizing moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia

[by the American College of Surgeons]

The following statement was approved by the ACS Board of Regents at its October 2003 meeting.

Over the past few years, there has been a noticeable increase in the number of invasive procedures being performed in the office setting. Recognizing that many states still haven't issued patient safety guidelines in this area, the American College of Surgeons (ACS) sponsored a resolution, which was passed at the American Medical Association's (AMA's) December 2002 Interim Meeting of its House of Delegates. In brief, the resolution called on the AMA to work with the ACS in "convening a work group of interested specialty societies and state medical associations to identify specific requirements for optimal office-based procedures and utilize those requirements to develop guidelines and model state legislation for use by state regulatory authorities to assure quality of office-based procedures."

On February 5, 2003, the ACS convened a meeting of interested surgical specialty societies to discuss the surgical community's perspective on this issue. In addition, the College invited representatives from the American Society of Anesthesiologists (ASA) to provide information and guidance regarding ASA's anesthesia guidelines. As a result of this meeting, a majority of the surgical community reached consensus on a set of 10

http://facs.org/fellows_info/statements/st-46.html

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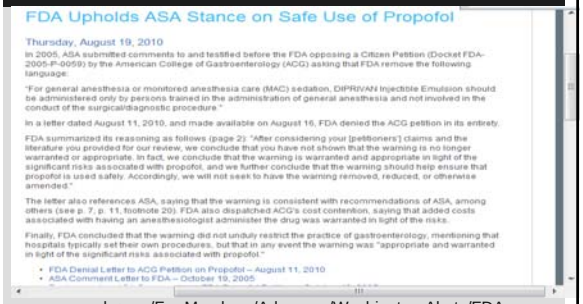
FDA Stance on Propofol



FDA Upholds ASA Stance on Safe Use of Propofol

Thursday, August 19, 2010

In 2005, ASA submitted comments to and testified before the FDA opposing a Citizen Petition (Docket FDA-2005-P-0059) by the American College of Gastroenterology (ACG) asking that FDA remove the following language:

"For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectible Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure."

In a letter dated August 11, 2010, and made available on August 16, FDA denied the ACG petition in its entirety.

FDA summarized its reasoning as follows (page 2): "After considering your [petitioners'] claims and the literature you provided for our review, we conclude that you have not shown that the warning is no longer warranted or appropriate. In fact, we conclude that the warning is warranted and appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. Accordingly, we will not seek to have the warning removed, reduced, or otherwise amended."

The letter also references ASA, saying that the warning is consistent with recommendations of ASA, among others (see p. 7, p. 11, footnote 20). FDA also dispatched ACG's cost contention, saying that added costs associated with having an anesthesiologist administer the drug was warranted in light of the risks.

Finally, FDA concluded that the warning did not unduly restrict the practice of gastroenterology, mentioning that hospitals typically set their own procedures, but that in any event the warning was "appropriate and warranted in light of the significant risks associated with propofol."

- FDA Denial Letter to ACG Petition on Propofol – August 11, 2010
- ASA Comment Letter to FDA – October 19, 2005

www.asahq.org/For-Members/Advocacy/Washington-Alerts/FDA-Upholds-ASA-Stance-on-Safe-Use-of-Propofol.aspx

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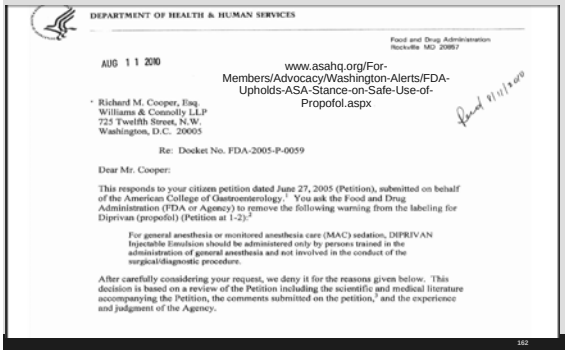
FDA Letter on Diprivan



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 11 2010

www.asahq.org/For-Members/Advocacy/Washington-Alerts/FDA-Upholds-ASA-Stance-on-Safe-Use-of-Propofol.aspx

Richard M. Cooper, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005

Re: Docket No. FDA-2005-P-0059

Dear Mr. Cooper:

This responds to your citizen petition dated June 27, 2005 (Petition), submitted on behalf of the American College of Gastroenterology.[1] You ask the Food and Drug Administration (FDA or Agency) to remove the following warning from the labeling for Diprivan (propofol) (Petition at 1-2):[2]

> For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.

After carefully considering your request, we deny it for the reasons given below. This decision is based on a review of the Petition including the scientific and medical literature accompanying the Petition, the comments submitted on the petition,[3] and the experience and judgment of the Agency.

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II. DISCUSSION

You request that FDA remove the warning from the propofol labeling stating that propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.[7] You state that propofol has several advantages over alternative sedation agents for endoscopic procedures but has a similar "risk profile" (Petition at 2). You claim the warning is no longer warranted because studies have established that propofol can be administered safely and effectively by medical professionals other than anesthesiologists and nurse anesthetists (Petition at 3-8). You believe that the requested labeling change will promote efficiency and reduce costs to payors by eliminating the need for an anesthesiologist or nurse anesthetist to be present to administer propofol during an endoscopic procedure (Petition at 1). You also suggest that the current warning places an unwarranted restriction on the ability of gastroenterologists to practice medicine (Petition at 1).

After considering your claims and the literature you provided for our review, we conclude that you have not shown that the warning is no longer warranted or appropriate. In fact, we conclude that the warning is warranted and appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. Accordingly, we will not seek to have the warning removed, reduced, or otherwise amended.

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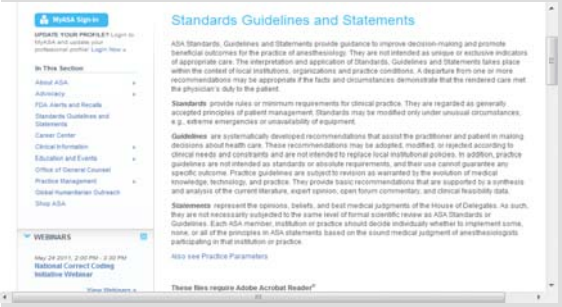
ASA Guidelines and Statements



www.asahq.org/publicationsAndServices/sgstoc.htm

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ASA Safe Use of Diprivan

STATEMENT ON SAFE USE OF PROPOFOL

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for deep sedation.

The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to rescue* patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.**

- The physician responsible for the use of sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.

  The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.
- The practitioner administering propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications.

  The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.
- During the administration of propofol, patients should be monitored without interruption to

http://www.asahq.org/publicationsAndServices/sgstoc.htm

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ASA Moderate Sedation Privileges

STATEMENT ON GRANTING PRIVILEGES FOR ADMINISTRATION OF MODERATE SEDATION TO PRACTITIONERS WHO ARE NOT ANESTHESIA PROFESSIONALS

Committee of Origin: Ad Hoc Committee on Credentialing

(Approved by the ASA House of Delegates on October 25, 2005, and amended on October 18, 2006)

The American Society of Anesthesiologists is vitally interested in the safe administration of anesthesia. As such, it has concern for any system or set of practices, used either by its members or the members of other disciplines that would adversely affect the safety of anesthesia administration. It has genuine concern that individuals, however well intentioned, who are not anesthesia professionals may not recognize that sedation and general anesthesia are on a continuum and thus deliver levels of sedation that are, in fact, general anesthesia without having the training and experience to recognize this state and respond appropriately.

The intent of this statement is to suggest a framework for granting privileges that will help ensure competence of individuals who administer or supervise the administration of moderate sedation. Only physicians, dentists or podiatrists who are qualified by education, training and licensure to administer moderate sedation should supervise the administration of moderate sedation. This statement can be used by any facility—hospital, ambulatory care or physician's, dentist's or podiatrist's office—in which an internal or external credentialing process is required for administration of sedative and analgesic drugs to establish a level of moderate sedation.

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ASA Granting Privileges for Deep Sedation

STATEMENT ON GRANTING PRIVILEGES FOR DEEP SEDATION TO NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS

Committee of Origin: *Ad Hoc* on Non-Anesthesiologist Privileging

(Approved by the ASA House of Delegates on October 20, 2010)

1. INTRODUCTION

The American Society of Anesthesiologists is vitally interested in the safe administration of all anesthesia services including moderate and deep sedation. As such, it has concern for any system or set of practices, used either by its members or the members of other disciplines that would adversely affect the safety of anesthesia or sedation administration. It has genuine concern that individuals, however well intentioned, who are not anesthesia professionals may not recognize that sedation and general anesthesia are on a continuum, and thus deliver levels of sedation that may, in fact, be general anesthesia without having the training and experience to respond appropriately.

ASA believes that anesthesiologist participation in all deep sedation is the best means to achieve the safest care. ASA acknowledges, however, that Medicare regulations permit some non-anesthesiologists to administer or supervise the administration of deep sedation. This advisory should not be consadered as an endorsement, or absolute condemnation, of this practice by ASA but rather to serve as a potential guide to its members who may be called upon by administrators or others to provide input in this process. This document provides a framework to identify those physicians, dentists, oral surgeons or podiatrists who may potentially qualify to administer or supervise the administration of deep sedation.

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ASA Guidelines for Privileges

GUIDELINES FOR DELINEATION OF CLINICAL PRIVILEGES IN ANESTHESIOLOGY

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 15, 2003, and last amended on October 22, 2008)

The following guidelines are designed to assist anesthesiologists and organizations in developing a program for the delineation of clinical privileges in anesthesiology. The guidelines are meant to apply to physicians practicing anesthesiology within an organization that has a formal process for delineating privileges and a program of peer review that evaluates the clinical performance and patient care results of physicians who are granted clinical privileges in anesthesiology.

Anesthesiology is the practice of medicine. Clinical privileges in anesthesiology are granted to physicians who are qualified by training to render patients insensible to pain and to minimize stress during surgical, obstetrical and certain medical procedures using general anesthesia, regional anesthesia or monitored anesthesia care. Performance of preanesthetic, intra-anesthetic and postanesthetic evaluation and management are essential components of the practice of anesthesiology.

The granting, reappraisal and revision of clinical privileges should be awarded on a time-limited basis in accordance with medical staff bylaws and institutional/facility and governmental rules and regulations, as applicable.

To be awarded medical staff privileges in anesthesiology, a physician must fully meet certain required criteria. It is possible to make all the following criteria mandatory or to have a mixture of

www.asahq.org/publicationsAndServices/sgstoc.htm

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ASA Anesthesiologist in Charge of Case

Safe Conduct of the Anesthesia Care Team

In order to achieve optimum patient safety, the anesthesiologist who directs the Anesthesia Care Team is responsible for the following:

1. **Management of personnel** – Anesthesiologists should assure the assignment of appropriately skilled physician and/or nonphysician personnel for each patient and procedure.
2. **Preanesthetic evaluation of the patient** – A preanesthetic evaluation allows for the development of an anesthetic plan that considers all conditions and diseases of the patient that may influence the safe outcome of the anesthetic. Although nonphysicians may contribute to the preoperative collection and documentation of patient data, the anesthesiologist is responsible for the overall evaluation of each patient.
3. **Prescribing the anesthetic plan** – The anesthesiologist is responsible for prescribing an anesthesia plan aimed at the greatest safety and highest quality for each patient. The anesthesiologist discusses with the patient (when appropriate), the anesthetic risks, benefits and alternatives, and obtains informed consent. When a portion of the anesthetic care will be performed by another qualified anesthesia provider, the anesthesiologist should inform the patient that delegation of anesthetic duties is included in care provided by the Anesthesia Care Team.

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ASA Supervision of CRNAs

Supervision of Nurse Anesthetists by Surgeons

Note: In this paragraph "surgeon(s)" may refer to any appropriately trained, licensed and credentialed nonanesthesiologist who may supervise nurse anesthetists.

General, regional and monitored anesthesia care all expose patients to risks. Nonanesthesiologist physicians may not possess the expertise that uniquely qualifies and enables anesthesiologists to manage the most clinically challenging medical situations that arise during the perioperative period. While a few surgical training programs provide some anesthesiology specific education (e.g., some oral and maxillofacial residencies), no surgical, dental, podiatric or any other nonanesthesiology training programs provide enough training specific to anesthesiology to enable their graduates to provide the level of medical supervision and clinical expertise that anesthesiologists provide. However, surgeons can still significantly add to patient safety and quality of care by assuming medical responsibility for all perioperative care when an anesthesiologist is not present. Anesthetic and surgical complications often arise unexpectedly

Anesthesia Care Team 2009 at http://www.asahq.org/publicationsAndServices/sgstoc.htm

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ASA Supervision of CRNAs

STATEMENT ON THE ANESTHESIA CARE TEAM

and require immediate medical diagnosis and treatment. Even if state law or regulation says a surgeon is not "required" to supervise nonphysician anesthesia providers, the surgeon may be the only medical doctor on site. Whether the need is preoperative medical clearance or intraoperative resuscitation from an unexpected complication, the surgeon, both ethically and according to training and ability, should be expected to provide medical oversight or supervision of all perioperative health care provided, including nonphysician nurse anesthesia care. To optimize patient safety, careful consideration is required when surgeons can be expected to be the only medical doctor available to provide oversight of all perioperative care. This is especially true in freestanding surgery centers and surgeons' offices where, in the event of unexpected emergencies, consultation with other medical specialists frequently is not available. In the event of unexpected emergencies, lack of immediately available and appropriately trained physician support can reduce the likelihood of successful resuscitation. This should always be a consideration when deciding which procedures should be performed in these settings, and on which patients, particularly if the individual supervising the nurse anesthetist is not a medical doctor with training appropriate for providing critical perioperative medical management.

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ASA Granting Privileges for Deep Sedation

STATEMENT ON GRANTING PRIVILEGES FOR DEEP SEDATION TO NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS

2. ADVISORY

This advisory is designed to assist health care facilities in developing a program for the delineation of clinical privileges for practitioners who are not anesthesia professionals to administer sedative and analgesic drugs to establish a level of deep sedation. They are written to apply to every setting in which an internal or external privileging process is required for granting privileges to administer sedative and analgesic drugs to establish a level of deep sedation (e.g., hospital, freestanding procedure center, ambulatory surgery center, physician's or dentist's office, etc.). These recommendations do not lead to the granting of privileges to administer general anesthesia.

The granting, reappraisal and revision of clinical privileges will be awarded on a time-limited basis in accordance with rules and regulations of the health care facility, its medical staff, organizations accrediting the health care facility, and relevant local, state and federal governmental agencies.

NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS

Note: The *Hospital Anesthesia Services Condition of Participation 42 CFR 482.52(a)* limits the administration of deep sedation to "qualified anesthesia professionals" within their scope of practice. CMS defines these personnel specifically as an anesthesiologist; non-

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ASA Anesthesiologist in Charge of Case

4. **Management of the anesthetic** – The management of an anesthetic is dependent on many factors including the unique medical conditions of individual patients and the procedures being performed. Anesthesiologists should determine which perioperative tasks, if any, may be delegated. The anesthesiologist may delegate specific tasks to qualified nonanesthesiologist members of the ACT providing that quality of care and patient safety are not compromised, but should participate in critical parts of the anesthetic and remain immediately physically available for management of emergencies regardless of the type of anesthetic (see **Addendum B**).
5. **Postanesthesia care** – Routine postanesthesia care is delegated to postanesthesia nurses. The evaluation and treatment of postanesthetic complications are the responsibility of the anesthesiologist.
6. **Anesthesia consultation** – Like other forms of medical consultation, this is the practice of medicine and should not be delegated to nonphysicians.

www.asahq.org/publicationsAndServices/sgstoc.htm

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ACEP Policies

http://www.acep.org/content.aspx?id=30060

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PAIN MANAGEMENT/CLINICAL POLICY

Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department

From the American College of Emergency Physicians Clinical Policies Subcommittee (Writing Committee) on Procedural Sedation and Analgesia:
Steven A. Godwin, MD, Chair
David A. Caro, MD
Stephen J. Wolf, MD
Andy S. Jagoda, MD
Ronald Charles, MD
Benjamin E. Marett, RN, MSN, CEN, CNA, COHN-S (ENA Representative 2002-2003)
Jessie Moore, RN, MSN, CEN (ENA Representative 2001-2002)

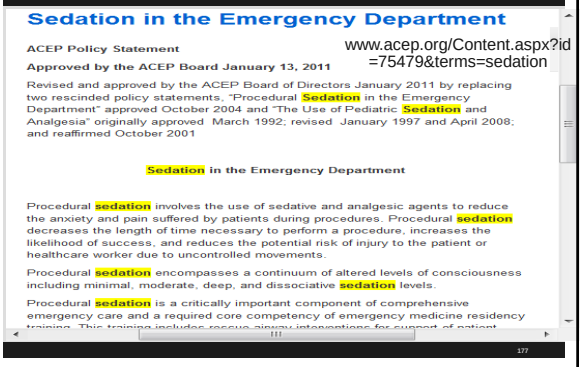
www.acep.org/content.aspx?id=30060

Members of the American College of Emergency Physicians Clinical Policies Committee (Oversight Committee) included:
William C. Dolsey, MD (Chair 2000-2002, Co-Chair 2002-2003)
Andy S. Jagoda, MD (Co-Chair 2002-2003, Chair 2003-2005)
Michael Moon, RN, CNS, MSN, CEN (ENA Representative 2003-2004)
Jessie Moore, RN, MSN, CEN (ENA Representative 2001-2002)

ACEP Policy Statements

www.acep.org/policystatements/?pg=2

ACEP 2011 Sedation in the ED



Sedation in the Emergency Department

ACEP Policy Statement

Approved by the ACEP Board January 13, 2011

Revised and approved by the ACEP Board of Directors January 2011 by replacing two rescinded policy statements, "Procedural Sedation in the Emergency Department" approved October 2004 and "The Use of Pediatric Sedation and Analgesia" originally approved March 1992; revised January 1997 and April 2008; and reaffirmed October 2001

Sedation in the Emergency Department

Procedural sedation involves the use of sedative and analgesic agents to reduce the anxiety and pain suffered by patients during procedures. Procedural sedation decreases the length of time necessary to perform a procedure, increases the likelihood of success, and reduces the potential risk of injury to the patient or healthcare worker due to uncontrolled movements.

Procedural sedation encompasses a continuum of altered levels of consciousness including minimal, moderate, deep, and dissociative sedation levels.

Procedural sedation is a critically important component of comprehensive emergency care and a required core competency of emergency medicine residency

www.acep.org/Content.aspx?id=75479&terms=sedation

The American College of Emergency Physicians is the authoritative body for the establishment of guidelines for **sedation** of patients in the emergency setting. To promote the safe and effective use of **sedation** in emergency department patients, the American College of Emergency Physicians recommends the following:

- Emergency physicians who have received the appropriate training and skills necessary to safely provide procedural **sedation** should be eligible for credentialing in all levels of procedural **sedation**.
- The decision to provide **sedation** and the selection of the specific pharmacologic agents should be individualized for each patient by the emergency physician and should not be otherwise restricted.
- Emergency physicians and staff are expected to be familiar with the pharmaceutical agents they use and be prepared to manage their potential complications.
- To minimize complications, the appropriate drugs and dosages must be chosen and administered in an appropriately monitored setting, and a patient evaluation should be performed before, during, and after their use.
- Institutional and departmental guidelines related to the **sedation** of patients should include credentialing and verification of competency of providers, selection and preparation of patients, informed consent, equipment and monitoring requirements, staff training and competency verification, criteria for discharge, and continuous quality improvement.

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ENA and ACEP Position

Clinical & Practice Management

- Clinical Policies
- Policy Statements
- Resources
- EMS & Disaster Preparedness
- Find a Physician Group
- Residency Programs
- Journals and Publications

Delivery of Agents for Procedural Sedation and Analgesia by Emergency Nurses

Approved by the ACEP Board of Directors April 2005 and the Emergency Nurses Association (ENA) Board March 2005

Published simultaneously, October 2005, in *Journal of Emergency Nursing* and *Annals of Emergency Medicine*

The Emergency Nurses Association (ENA) and the American College of Emergency Physicians (ACEP) support the delivery of medications used for procedural **sedation** and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam.

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ACEP Rapid Sequence Intubation

Rapid-Sequence Intubation

Reaffirmed by the ACEP Board of Directors October 2006
Reaffirmed by the ACEP Board of Directors October 2000
Originally approved by the ACEP Board of Directors September 1996

Rapid-sequence intubation (RSI) is an important technique for airway management of patients in the emergency department and is in the domain of emergency medicine practice. RSI is defined as a technique where a potent sedative or induction agent is administered virtually simultaneously with a paralyzing dose of a neuromuscular blocking agent to facilitate rapid tracheal intubation. The technique includes specific protection against aspiration of gastric contents, provides excellent access to the airway for intubation, and permits pharmacologic control of adverse responses to illness, injury, and the intubation itself. The American College of Emergency Physicians recognizes the role of RSI in modern emergency care and supports the following principles.

- Physicians performing RSI should possess training, knowledge, and experience in the techniques and pharmacologic agents used to perform RSI.
- Neuromuscular blocking agents and appropriate sedative and induction agents should be immediately available in the ED and accessible to all physicians who perform RSI in the ED.
- Quality review and patient monitoring should be addressed when policies about RSI are developed in the ED.

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Level B recommendations. Propofol can be safely administered for procedural sedation and analgesia in the ED.

VII. Can ketamine, midazolam, fentanyl, propofol, and etomidate be safely administered for procedural sedation and analgesia in the ED?

Agents such as ketamine result in a dissociative state in which a patient may not speak or respond purposefully to verbal commands. Use of ketamine in the doses recommended for procedural sedation and analgesia does not result in a loss of protective reflexes. The medical literature documents the safety of its use for procedural sedation and analgesia in pediatric populations.[34,35,67] In a well-designed randomized controlled trial in 260 children aged 5 to 15 years, Kennedy et al[67] found that a ketamine and midazolam combination was safer and more efficacious than a fentanyl and midazolam combination for sedation in orthopedic procedures. Hypoxia occurred in 6% of patients receiving ketamine and midazolam versus 20% of patients in the fentanyl and midazolam group. Efficacy as determined by objective measures of physician and parental satisfaction were thought to be superior in the ketamine and midazolam study arm.[67] In a consecutive case series of 1,022 children, Green et al[35] report that ketamine at doses of 4 to 5 mg/kg intramuscularly produced adequate sedation in 98% of children. They reported airway complications in 1.4% of patients that included laryngospasm, apnea, and respiratory depression, all of which were quickly identified and treated without intubation or sequelae. Emesis occurred in 6.7% without evidence of aspiration.

induced procedural sedation was reported to have the lowest rate of respiratory depression when compared with methohexital, fentanyl/midazolam, and etomidate.[71] There were no significant complications. A prospective randomized trial with 103 patients receiving propofol or methohexital within the ED compared the depth of sedation with Bispectral Index scores and rates of respiratory depression assessed by $ETCO_2$. Of note, approximately one half of the patients in both groups met predefined criteria for respiratory depression. The study did not detect a difference in either the level of sedation by Bispectral Index or the level of subclinical respiratory depression between the 2 agents. The authors found no significant adverse events with either sedative.[28] In another prospective study of 43 children comparing midazolam and propofol, the authors reported successful sedation but also significant hypoxemia and oversedation; however, no significant complications were reported.[72] In another pediatric study involving 40 patients, Sheikan et al[36] reported a significant incidence of oxygen desaturation; however, again, there were no clinical sequelae.

The literature regarding safety and efficacy of etomidate in the ED is also mounting. A prospective, double-blinded, randomized trial of 46 adult patients undergoing anterior shoulder dislocation reduction in the ED compared midazolam with etomidate.[37] Burton et al[37] found approximately a 90% procedural success rate for both groups. Patients experienced no episodes of hypotension or arrhythmia. Adverse respiratory

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PEDIATRICS/CLINICAL POLICY

Clinical Policy: Critical Issues in the Sedation of Pediatric Patients in the Emergency Department

From the EMSC Panel (Writing Committee) on Critical Issues in the Sedation of Pediatric Patients in the Emergency Department:
Sharon E. Mace, MD, Chair, American College of Emergency Physicians (ACEP)
Lance A. Brown, MD, MPH (ACEP)
Lisa Francis, BSN, RN (Society of Pediatric Nurses)
Steven A. Godwin, MD (ACEP)
Sigrid A. Hahn, MD (ACEP)
Patricia Kunz Howard, PhD, RN, CEN (Emergency Nurses Association)
Robert M. Kennedy, MD (American Academy of Pediatrics)
David P. Mooney, MD (American Pediatric Surgical Association)
Alfred D. Sacchetti, MD (ACEP)
Robert L. Weaes, MD, MS, Methodologist (ACEP)
Randall M. Clark, MD (American Society of Anesthesiologists)

Other members of the EMSC Panel included:
Ramon W. Johnson, MD (ACEP Board Liaison)
Rhonda R. Whitson, RHIA (Clinical Policies Manager, ACEP)
Tuel Doong (Vice President, The Nakamoto Group, Inc)
Jenni Nakamoto-Yingling (President, The Nakamoto

Approved by the ACEP Board of Directors, October 5, 2007
Supported by the Emergency Nurses Association, October 5, 2007
Endorsed by the Society of Pediatric Nurses, November 3, 2007
Endorsed by the American Pediatric Surgical Association, December 20, 2007

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ACEP Letter to Members 2-10-2011

February 10, 2011

Dear ACEP Member:

One of the core competencies of an emergency physician is procedural sedation. Our clinical policies have outlined the evidence that we are skilled in the area of analgesia, sedation, and emergency airway management. The Centers for Medicare & Medicaid Services (CMS) has revised its interpretive guidelines for anesthesia services. Hospitals are to use these guidelines in developing their individual credentialing policies. These guidelines and their FAQs note that " . . . emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to general)." This change in CMS' guidelines is the result of vigorous efforts by ACEP leadership and staff working with others to achieve this result.

The CMS document also suggests that hospitals should use specialty-specific guidelines in creating their credentialing policies and specifically cites ACEP's clinical policy on sedation, and quotes the Emergency Nurses Association (ENA) and ACEP to "support the delivery of medications used for procedural sedation and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam."

Recently, the American Society of Anesthesiologists (ASA) issued their "Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners." After ACEP leaders met with the ASA, they wrote the attached letter of clarification. Of note, their statement and this letter preceded the CMS revision noted above.

We believe, based on the CMS interpretive guidelines and the ASA's letter of clarification, that physicians who are residency trained and/or board certified by ABEM/AOBEM in emergency medicine

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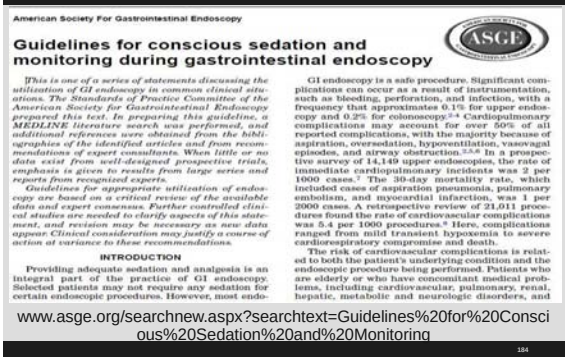
American Society for GI Endoscopy



American Society For Gastrointestinal Endoscopy

Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy

This is one of a series of statements discussing the utilization of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

INTRODUCTION

Providing adequate sedation and analgesia is an integral part of the practice of GI endoscopy. Selected patients may not require any sedation for certain endoscopic procedures. However, most endoscopic procedures. However, most endoscopy is a safe procedure. Significant complications can occur as a result of instrumentation, such as bleeding, perforation, and infection, with a frequency that approximates 0.1% for upper endoscopy and 0.2% for colonoscopy.[1-4] Cardiopulmonary complications may account for over 50% of all reported complications, with the majority because of aspiration, oversedation, hypoventilation, vasovagal episodes, and airway obstruction.[2,5,6] In a prospective survey of 14,149 upper endoscopies, the rate of immediate cardiopulmonary incidents was 2 per 1000 cases.[7] The 30-day mortality rate, which included cases of aspiration pneumonia, pulmonary embolism, and myocardial infarction, was 1 per 2000 cases. A retrospective review of 21,011 procedures found the rate of cardiovascular complications was 5.4 per 1000 procedures.[8] Here, complications ranged from mild transient hypoxemia to severe cardiorespiratory compromise and death.

The risk of cardiovascular complications is related to both the patient's underlying condition and the endoscopic procedure being performed. Patients who are elderly or who have concomitant medical problems, including cardiovascular, pulmonary, renal, hepatic, metabolic and neurologic disorders, and

www.asge.org/searchnew.aspx?searchtext=Guidelines%20for%20Conscious%20Sedation%20and%20Monitoring

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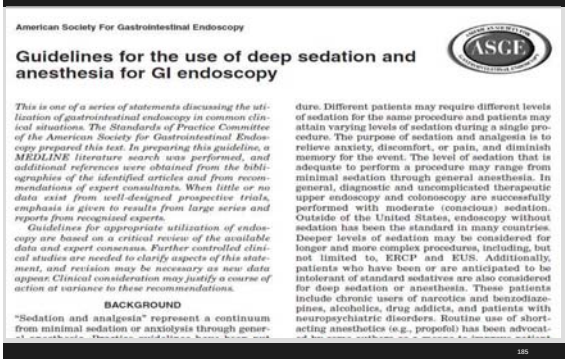
ASGE Guideline on Deep Sedation



American Society For Gastrointestinal Endoscopy

Guidelines for the use of deep sedation and anesthesia for GI endoscopy

This is one of a series of statements discussing the utilization of gastrointestinal endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

BACKGROUND

"Sedation and analgesia" represent a continuum from minimal sedation or anxiolysis through general anesthesia. Practice guidelines have been published dure. Different patients may require different levels of sedation for the same procedure and patients may attain varying levels of sedation during a single procedure. The purpose of sedation and analgesia is to relieve anxiety, discomfort, or pain, and diminish memory for the event. The level of sedation that is adequate to perform a procedure may range from minimal sedation through general anesthesia. In general, diagnostic and uncomplicated therapeutic upper endoscopy and colonoscopy are successfully performed with moderate (conscious) sedation. Outside of the United States, endoscopy without sedation has been the standard in many countries. Deeper levels of sedation may be considered for longer and more complex procedures, including, but not limited to, ERCP and EUS. Additionally, patients who have been or are anticipated to be intolerant of standard sedatives are also considered for deep sedation or anesthesia. These patients include chronic users of narcotics and benzodiazepines, alcoholics, drug addicts, and patients with neuropsychiatric disorders. Routine use of short-acting anesthetics (e.g., propofol) has been advocat-

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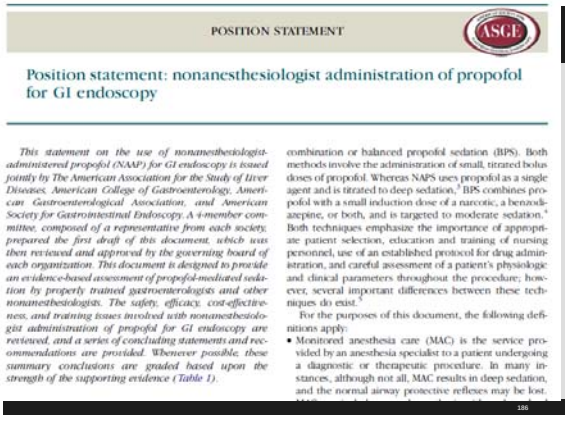

POSITION STATEMENT

Position statement: nonanesthesiologist administration of propofol for GI endoscopy

This statement on the use of nonanesthesiologist-administered propofol (NAAP) for GI endoscopy is issued jointly by The American Association for the Study of Liver Diseases, American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy. A 4-member committee, composed of a representative from each society, prepared the first draft of this document, which was then reviewed and approved by the governing board of each organization. This document is designed to provide an evidence-based assessment of propofol-mediated sedation by properly trained gastroenterologists and other nonanesthesiologists. The safety, efficacy, cost-effectiveness, and training issues involved with nonanesthesiologist administration of propofol for GI endoscopy are reviewed, and a series of concluding statements and recommendations are provided. Whenever possible, these summary conclusions are graded based upon the strength of the supporting evidence (Table 1).

combination or balanced propofol sedation (BPS). Both methods involve the administration of small, titrated bolus doses of propofol. Whereas NAPS uses propofol as a single agent and is titrated to deep sedation,[3] BPS combines propofol with a small induction dose of a narcotic, a benzodiazepine, or both, and is targeted to moderate sedation.[4] Both techniques emphasize the importance of appropriate patient selection, education and training of nursing personnel, use of an established protocol for drug administration, and careful assessment of a patient's physiologic and clinical parameters throughout the procedure; however, several important differences between these techniques do exist.[5]

For the purposes of this document, the following definitions apply:

- Monitored anesthesia care (MAC) is the service provided by an anesthesia specialist to a patient undergoing a diagnostic or therapeutic procedure. In many instances, although not all, MAC results in deep sedation, and the normal airway protective reflexes may be lost.

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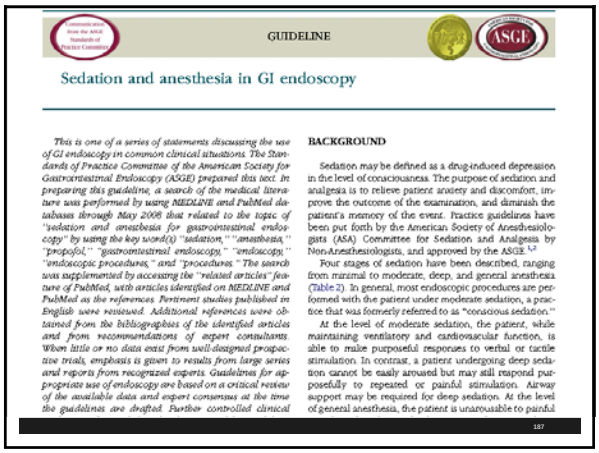

GUIDELINE

Sedation and anesthesia in GI endoscopy

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by using MEDLINE and PubMed databases through May 2006 that related to the topic of "sedation and anesthesia for gastrointestinal endoscopy" by using the key word(s) "sedation," "anesthesia," "propofol," "gastrointestinal endoscopy," "endoscopy," "endoscopic procedures," and "procedures." The search was supplemented by accessing the "related articles" feature of PubMed, with articles identified on MEDLINE and PubMed as the references. Pertinent studies published in English were reviewed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical

BACKGROUND

Sedation may be defined as a drug-induced depression in the level of consciousness. The purpose of sedation and analgesia is to relieve patient anxiety and discomfort, improve the outcome of the examination, and diminish the patient's memory of the event. Practice guidelines have been put forth by the American Society of Anesthesiologists (ASA) Committee for Sedation and Analgesia by Non-Anesthesiologists, and approved by the ASGE.[1,2]

Four stages of sedation have been described, ranging from minimal to moderate, deep, and general anesthesia (Table 2). In general, most endoscopic procedures are performed with the patient under moderate sedation, a practice that was formerly referred to as "conscious sedation."

At the level of moderate sedation, the patient, while maintaining ventilatory and cardiovascular function, is able to make purposeful responses to verbal or tactile stimulation. In contrast, a patient undergoing deep sedation cannot be easily aroused but may still respond purposefully to repeated or painful stimulation. Airway support may be required for deep sedation. At the level of general anesthesia, the patient is unarousable to painful

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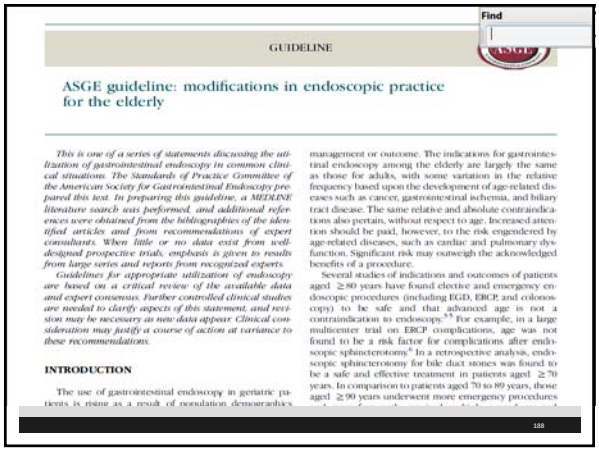

Find

GUIDELINE

ASGE guideline: modifications in endoscopic practice for the elderly

This is one of a series of statements discussing the utilization of gastrointestinal endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

INTRODUCTION

The use of gastrointestinal endoscopy in geriatric patients is rising as a result of population demographics

management or outcome. The indications for gastrointestinal endoscopy among the elderly are largely the same as those for adults, with some variation in the relative frequency based upon the development of age-related diseases such as cancer, gastrointestinal ischemia, and biliary tract disease. The same relative and absolute contraindications also pertain, without respect to age. Increased attention should be paid, however, to the risk engendered by age-related diseases, such as cardiac and pulmonary dysfunction. Significant risk may outweigh the acknowledged benefits of a procedure.

Several studies of indications and outcomes of patients aged ≥ 80 years have found elective and emergency endoscopic procedures (including EGD, ERCP, and colonoscopy) to be safe and that advanced age is not a contraindication to endoscopy.[3-5] For example, in a large multicenter trial on ERCP complications, age was not found to be a risk factor for complications after endoscopic sphincterotomy.[6] In a retrospective analysis, endoscopic sphincterotomy for bile duct stones was found to be a safe and effective treatment in patients aged ≥ 70 years. In comparison to patients aged 70 to 89 years, those aged ≥ 90 years underwent more emergency procedures

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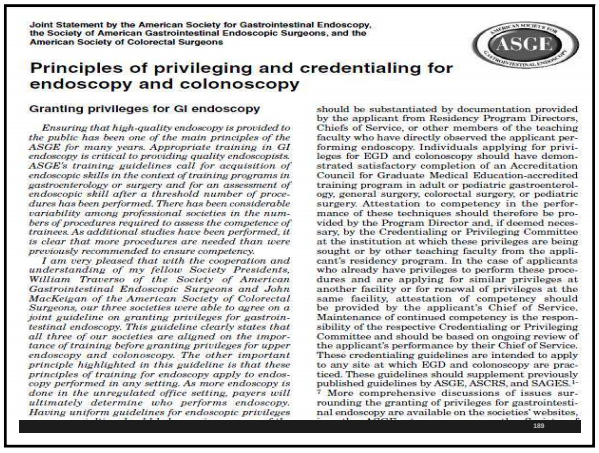

Joint Statement by the American Society for Gastrointestinal Endoscopy, the Society of American Gastrointestinal Endoscopic Surgeons, and the American Society of Colorectal Surgeons

Principles of privileging and credentialing for endoscopy and colonoscopy

Granting privileges for GI endoscopy

Ensuring that high-quality endoscopy is provided to the public has been one of the main principles of the ASGE for many years. Appropriate training in GI endoscopy is critical to providing quality endoscopists. ASGE's training guidelines call for acquisition of endoscopic skills in the context of training programs in gastroenterology or surgery and for an assessment of endoscopic skill after a threshold number of procedures has been performed. There has been considerable variability among professional societies in the numbers of procedures required to assess the competence of trainees. As additional studies have been performed, it is clear that more procedures are needed than were previously recommended to ensure competency.

I am very pleased that with the cooperation and understanding of my fellow Society Presidents, William Traverso of the Society of American Gastrointestinal Endoscopic Surgeons and John MacKeigan of the American Society of Colorectal Surgeons, our three societies were able to agree on a joint guideline on granting privileges for gastrointestinal endoscopy. This guideline clearly states that all three of our societies are aligned on the importance of training before granting privileges for upper endoscopy and colonoscopy. The other important principle highlighted in this guideline is that these principles of training for endoscopy apply to endoscopy performed in any setting. As more endoscopy is done in the unregulated office setting, payers will ultimately determine who performs endoscopy. Having uniform guidelines for endoscopic privileges

should be substantiated by documentation provided by the applicant from Residency Program Directors, Chiefs of Service, or other members of the teaching faculty who have directly observed the applicant performing endoscopy. Individuals applying for privileges for EGD and colonoscopy should have demonstrated satisfactory completion of an Accreditation Council for Graduate Medical Education-accredited training program in adult or pediatric gastroenterology, general surgery, colorectal surgery, or pediatric surgery. Attestation to competency in the performance of these techniques should therefore be provided by the Program Director and, if deemed necessary, by the Credentialing or Privileging Committee at the institution at which these privileges are being sought or by other teaching faculty from the applicant's residency program. In the case of applicants who already have privileges to perform these procedures and are applying for similar privileges at another facility or for renewal of privileges at the same facility, attestation of competency should be provided by the applicant's Chief of Service. Maintenance of continued competency is the responsibility of the respective Credentialing or Privileging Committee and should be based on ongoing review of the applicant's performance by their Chief of Service. These credentialing guidelines are intended to apply to any site at which EGD and colonoscopy are practiced. These guidelines should supplement previously published guidelines by ASGE, ASCRS, and SAGES.[1-7] More comprehensive discussions of issues surrounding the granting of privileges for gastrointestinal endoscopy are available on the societies' websites,

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Pre-procedural Assessment

STANDARDS OF PRACTICE

Minimum staffing requirements for the performance of GI endoscopy

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by using Publied. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.

This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clin-

endoscopic procedures, the endoscopy suite staff has 5 major responsibilities that include, but are not limited to, patient monitoring, documentation, and technical assistance.[3] Technical assistance includes such activities as application of abdominal pressure, manipulation of endoscopic accessory devices (eg, forceps, snares, balloons, bougies, cautery devices), manipulation of endoscopes (eg, maintaining endoscope position while the endoscopist performs complex tasks), and cleaning and preparation of endoscopes. Accreditation organizations recommend that endoscopy unit staff receive training appropriate to their responsibilities and document maintenance of competency periodically (eg, annually). Objective evidence pertaining to the relationship between endoscopy unit staffing levels and patient outcomes is lacking. Therefore, recommendations are based primarily on expert opinion and clinical experience.

ENDOSCOPY WITHOUT SEDATION

The majority of GI endoscopic procedures performed in the United States are performed with sedation. However, sigmoidoscopy and transnasal endoscopy are often

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ENDOSCOPIST-DIRECTED SEDATION

For those patients receiving moderate sedation for endoscopic procedures, the physician must perform a pre-procedural assessment to determine the suitability of the patient for sedation and then formulate a sedation plan. Under the supervision of the physician, the RN prepares and administers sedatives while monitoring the patient's vital signs, comfort, and clinical status to detect any intra-procedural complications.[4] Once the patient's level of sedation and vital signs are stable, the RN may perform minor, interruptible tasks (eg, biopsy or polypectomy).[5-7] In patients who require more intensive or prolonged endoscopic interventions (eg, difficult polypectomy, EUS/FNA, ERCP), a second assistant, who may be a UAP, LPN, or another RN, should assist in the procedure to allow the RN administering moderate sedation to remain focused on patient monitoring rather than technical assistance.

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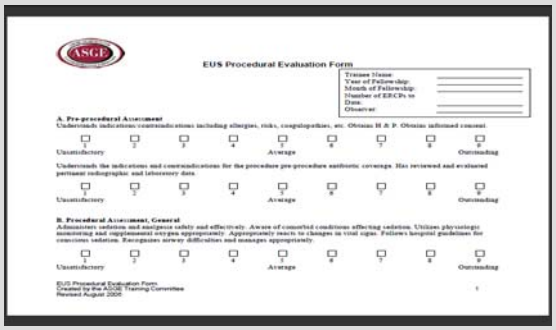
ASGE Evaluation Form



EUS Procedural Evaluation Form

Trainee Name:
Year of Fellowship:
Month of Fellowship:
Number of ERCPs to
Date:
Observer:

A. Pre-procedural Assessment

Understands indications/contraindications including allergies, risks, coagulopathies, etc. Obtains H & P. Obtains informed consent.

1 2 3 4 5 6 7 8 9
Unsatisfactory Average Outstanding

Understands the indications and contraindications for the procedure pre-procedure antibiotic coverage. Has reviewed and evaluated pertinent radiographic and laboratory data.

1 2 3 4 5 6 7 8 9
Unsatisfactory Average Outstanding

B. Procedural Assessment, General

Administers sedation and analgesia safely and effectively. Aware of comorbid conditions affecting sedation. Utilizes physiologic monitoring and supplemental oxygen appropriately. Appropriately reacts to changes in vital signs. Follows hospital guidelines for conscious sedation. Recognizes airway difficulties and manages appropriately.

1 2 3 4 5 6 7 8 9
Unsatisfactory Average Outstanding

EUS Procedural Evaluation Form
Created by the ASGE Training Committee
Revised August 2005

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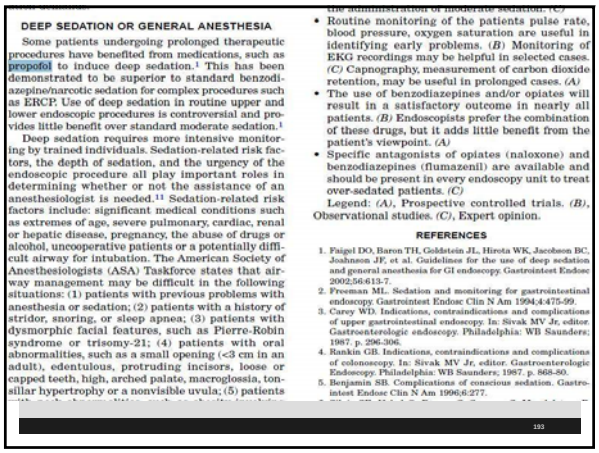

DEEP SEDATION OR GENERAL ANESTHESIA

Some patients undergoing prolonged therapeutic procedures have benefited from medications, such as propofol to induce deep sedation.[1] This has been demonstrated to be superior to standard benzodiazepine/narcotic sedation for complex procedures such as ERCP. Use of deep sedation in routine upper and lower endoscopic procedures is controversial and provides little benefit over standard moderate sedation.[1]

Deep sedation requires more intensive monitoring by trained individuals. Sedation-related risk factors, the depth of sedation, and the urgency of the endoscopic procedure all play important roles in determining whether or not the assistance of an anesthesiologist is needed.[11] Sedation-related risk factors include: significant medical conditions such as extremes of age, severe pulmonary, cardiac, renal or hepatic disease, pregnancy, the abuse of drugs or alcohol, uncooperative patients or a potentially difficult airway for intubation. The American Society of Anesthesiologists (ASA) Taskforce states that airway management may be difficult in the following situations: (1) patients with previous problems with anesthesia or sedation; (2) patients with a history of stridor, snoring, or sleep apnea; (3) patients with dysmorphic facial features, such as Pierre-Robin syndrome or trisomy-21; (4) patients with oral abnormalities, such as a small opening (<3 cm in an adult), edentulous, protruding incisors, loose or capped teeth, high, arched palate, macroglossia, tonsillar hypertrophy or a nonvisible uvula; (5) patients

the administration of moderate sedation. (C)

- Routine monitoring of the patients pulse rate, blood pressure, oxygen saturation are useful in identifying early problems. (B) Monitoring of EKG recordings may be helpful in selected cases. (C) Capnography, measurement of carbon dioxide retention, may be useful in prolonged cases. (A)
- The use of benzodiazepines and/or opiates will result in a satisfactory outcome in nearly all patients. (B) Endoscopists prefer the combination of these drugs, but it adds little benefit from the patient's viewpoint. (A)
- Specific antagonists of opiates (naloxone) and benzodiazepines (flumazenil) are available and should be present in every endoscopy unit to treat over-sedated patients. (C)

Legend: (A), Prospective controlled trials. (B), Observational studies. (C), Expert opinion.

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3. Carey WD. Indications, contraindications and complications of upper gastrointestinal endoscopy. In: Sivak MV Jr, editor. Gastroenterologic endoscopy. Philadelphia: WB Saunders; 1987. p. 296-306.
4. Rankin GB. Indications, contraindications and complications of colonoscopy. In: Sivak MV Jr, editor. Gastroenterologic Endoscopy. Philadelphia: WB Saunders; 1987. p. 868-80.
5. Benjamin SB. Complications of conscious sedation. Gastrointest Endosc Clin N Am 1996;6:277.

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Sedationfacts.org Coming Soon

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TJC Levels of Sedation and Anesthesia

- Minimal sedation (anxiolysis)-A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
- Moderate sedation/analgesia (conscious sedation)-A drug-induced depression of consciousness during which patients respond purposefully to verbal commands,6 either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained

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TJC Definition of Deep Sedation

- Deep sedation/analgesia-A drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation.
- The ability to independently maintain ventilatory function may be impaired.
- Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate.
- Cardiovascular function is usually impaired.

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TJC Definition of Anesthsia

- Anesthesia-Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia.
- General anesthesia is a drug-induced consciousness during which patients are not arousable, even by painful stimulation.
- The ability to independently maintain ventilatory function is often impaired.
- Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

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Operative & High Risk Procedures PC.03.01.03

- The hospital plans operative or other high-risk procedures
  - This includes moderate or deep sedation or anesthesia
  - Equipment identified in the EPs is available to the OR suites
  - Standards apply in any setting for epidural, spinal, MAC, general, moderate or deep sedation

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Operative & High Risk Procedures

- EP1 Those administering moderate or deep sedation and anesthesia are qualified
  - Must have credentials to manage and rescue patients at what ever level of anesthesia or sedation
- EP2 Must have sufficient number of qualified staff to evaluate the patient, provide the sedation and/or anesthesia, help with the procedure, and monitor and recover the patient
- EP5 RN supervises perioperative nursing care
  - Such as a RN Director of the OR

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Operative & High Risk Procedures

- EP6 Need equipment to monitor the patient's physiological status during moderate or deep sedation during surgery or high risk procedures
  - Example could include cardiac monitor, blood pressure machine, pulse oximetry, end tidal CO2 etc.
- EP7 Must have equipment to administer IV fluids, medications, blood and blood components during moderate and deep sedation for surgery or high risk procedures
  - Ivs, IV tubings, IV pumps, blood tubing, etc.

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Operative & High Risk Procedures

- EP8 Must have resuscitation equipment available for surgery or high risk procedures when using moderate or deep sedation and anesthesia
  - Endotracheal tubes, ambu bags, oxygen, defib, cardioverter, etc.
- EP10 Anesthesia is administered by qualified person (DS)
  - CRNA, anesthesiologist, or AA
  - Qualified physician other than an anesthesiologist
  - CRNA in 35 states must be supervised by anesthesiologist or operating surgeon

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Care Before Surgery or High Risk Procedure

- PC.03.01.03 states that the hospital provides the patient with care before surgery or the procedure
  - The following includes patient having moderate or deep sedation or anesthesia for surgery or a high risk procedure
- EP1 Conduct a presedation or preanesthesia assessment
  - RC.02.01.01 requires this be documented
  - CMS includes a requirement that the preanesthesia assessment be done and what should be in it
  - ASA and AANA has standards of practice on this

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Care Before Surgery or High Risk Procedure

- EP2 Assesses the patient's anticipated needs in order to plan for the post procedure care
- EP3 Do a preprocedural treatment according the patient's plan for care
- EP4 Provide the patient with preprocedural education, according to their plan of care
- EP7 LIP must review the plan and concur with the plan for sedation or anesthesia
- EP8 Reevaluate the patient immediately before administering deep sedation or anesthesia

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Care Before Surgery or High Risk Procedure

- EP18 A preanesthesia evaluation is completed and documented by an individual qualified to administer anesthesia within 48 hours prior
  - CMS measures the 48 hour time frame from when the first drug is given to introduce anesthesia
  - CMS has specific criteria that must be included in the pre and postanesthesia evaluation
  - ASA and AANA has standards of care related to the postanesthesia evaluation

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Monitoring During Surgery or Procedure

- PC.03.01.05 states that the hospital monitors the patient during surgery or other high-risk procedures
  - Patient must also be monitored during the administration of moderate or deep sedation or anesthesia
- EP1 The patient's oxygenation, ventilation, and circulation are monitored continuously during any of the above
  - RC.02.01.03 EP8 requires that this be documented in the medical record including medications, vital signs, level of consciousness, IV fluids or blood given, complications or any unanticipated events

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Monitoring During Surgery or Procedure

- CMS also requires monitoring during surgery or anesthesia administration
- CMS has new elements in the hospital CoPs about what must be documented by anesthesia during surgery
- Best to use a form to capture all of the required elements
- Be aware of the ASA and AANA standards of care and practice

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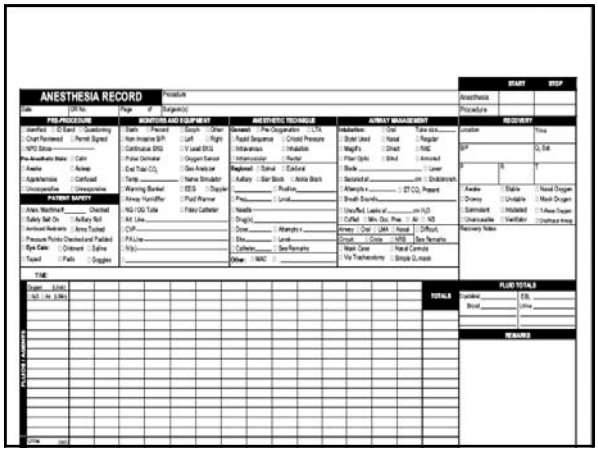
ANESTHESIA RECORD

Postanesthesia or Post Procedure Care

- PC.03.01.07 states that care must be provided to the patient after anesthesia, moderate, or deep sedation
- EP1 Need to assess their physiological status immediately after the above
- EP2 Must monitors the patient's physiological status, mental status, and pain level
- EP4 A qualified LIP discharges the patient from the PACU or from the hospital or uses approved discharge criteria
  - Many PACUs use Aldrete score

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Postanesthesia or Post Procedure Care

- EP6 Outpatients who have had sedation or anesthesia are discharged in the company of an individual who accepts responsibility for the patient
  - Should take patient out in a wheelchair and make sure they get into the car safely
- EP7 Qualified person does postanesthesia evaluation no later 48 hours after surgery or a procedure requiring anesthesia services
  - CMS has a CoP on the postanesthesia evaluation
  - The 48 hour time frame is measured from the time the patient hits the PACU or recovery area

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Postanesthesia or Post Procedure Care

- EP8 Postanesthesia evaluation for anesthesia recovery is completed as required by law and the hospital's P&P
  - CMS is very specific as to what must be included in the postanesthesia evaluation
  - Consider having a form to capture all of the required elements
  - ASA (American Society of Anesthesiologist) and American Association of Nurse Attorneys (AANA) have standards of care on postanesthesia evaluations

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Thank you for attending!

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