MEDICARE AMBULATORY SURGICAL CENTER (ASC)

ACCREDITATION STANDARDS MANUAL

Version 9.0, Effective April 7, 2025

AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES

TABLE OF CONTENTS

SURVEY INSTRUCTIONS

Please complete the Standards Manual for the facility by assessing compliance with the standards contained in this book.

STANDARDS STRUCTURE

Standards found in this book are organized by grouping relevant standards together. These groupings are comprised of “Sections,” “Sub-sections,” and then individual standard numbers. Each main “Section” is identified by a numerical value, “Sub-sections” have been assigned an alphabetical value, and the individual standards under the subsection have also been numbered. Based on this format, each standard has been assigned a unique identifier to include all three elements to indicate its location.

For example: The standard which states, “Each operating room is properly cleaned, maintained and free of litter and clutter” is the fourth standard under Section 2, Sub-section C. Therefore, the unique identifier for this standard is: 2-C-4.

Please note that not all standards are necessarily in continuous sequential order. Some numbers have been reserved for future use and do not appear in the manual. The groupings within the Sections and Sub-sections of this book are intended to separate standards into logical sets of standards. Based on 40 years’ experience, such groups are likely, but not guaranteed, to be found and assessed during the same portion of the survey process.

STANDARDS BOOK LAYOUT

The standards manual layout consists of five columns. The function of each column are as follows:

ID:

This column contains the alphanumerical identifier for each standard.

Standard:

This column contains the text for each standard.

CMS Ref:

This column indicates the corresponding CMS regulatory reference, if applicable.

Class:

This column indicates the anesthesia classification, based on QUAD A definitions, that is applicable to the standard. Only facilities that provide anesthesia meeting the definition of one or more of the classifications listed in this column are required to comply with that particular standard.

Score:

This column is used to document compliance or non-compliance by the surveyor during the survey process; or, by the facility during self-assessment reviews for performance. As stated below, if 100% compliance is not achieved, the standard is marked as “deficient”.

SCORING COMPLIANCE

The QUAD A accreditation program requires 100% compliance with each standard to become and remain accredited. There are no exceptions. If there is even one instance where a surveyor makes an observation of non-compliance, the standard is scored as “Deficient” and the facility will be required to submit a Plan of Correction, as well as evidence of completed corrections. There may be occasion where the surveyor observes non-compliance, but the facility is able to demonstrate that the deficiency has been corrected while the surveyor is still on-site. Applicable standard(s) will be given a score of deficient. To provide full context to QUAD A and CMS, the survey findings should illustrate that non-compliance was corrected in the presence of the survey team.

QUAD A does not confer accreditation until a facility has provided acceptable plans of correction and evidence of corrections for every deficiency cited. However, when a standard refers to "appropriate," "proper," or "adequate", reasonable flexibility and room for consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised.

NOTES:

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ANESTHESIA CLASS REQUIREMENTS

If a facility is not in compliance with any item in this document, standard 1-A-1 will be scored as deficient.

1. **Class A** (Facility must meet every Class "A" requirement)**:**

All surgical and procedural cases are performed in the facility under local, topical anesthesia, minimal sedation, or nitrous oxide using a standalone system for administration.

NOTE: Endotracheal tubes and supraglottic airways are permitted in the facility for emergency use only.

Local or Topical Anesthesia may be administered by any of the following:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA) under the supervision of an anesthesiologist
- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Registered nurse under the direct supervision of a credentialed physician as permitted by state law.

Nitrous Oxide may be administered using a Nitrous-Oxide Delivery System with required safety features by a credentialed:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Pediatric Dentist
- Dental Anesthesiologist
- Oral and Maxillofacial Surgeon (OMS)
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)
- Dental Assistant under the supervision of a Pediatric Dentist or Dental Anesthesiologist in accordance with State law.
- Registered Nurse under the direct supervision of a credentialed physician.

Clarifications:

- All cases performed in a Class A facility must be performed using local anesthesia with minimal sedation only. A Class A facility is not permitted to perform any cases with moderate sedation.
- No more than 500cc of liposuction aspirate may be removed.

- A single dose of analgesic or minimal sedation (anxiolytic) drug may be administered preoperatively, which results in minimal sedation, and one (1) dose of the same medication may be administered postoperatively. Any additional doses or agents are considered Moderate Sedation, requiring the facility to be accredited under Class B or C standards. This includes doses taken by patients prior to arriving at the facility.
- The use of propofol, spinal anesthesia, epidural anesthesia, endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.
- Nitrous oxide and minimal sedation are not permitted to be administered together in a Class A facility; they are only permitted in Class B and C facilities.
- If a facility performs procedures by administering oral medications (e.g., Valium) and/or performing nerve blocks (inter scalene, supraclavicular, femoral, etc.) or field blocks (e.g., retrobulbar, digital, Bier, etc.), this practice is considered Class B. The use of field or nerve blocks is **not** permitted in facilities accredited under facility Class A accreditation standards.

2. **Class B** (Facility must meet every Class "A" and "B" requirement)**:**

Surgical and procedural cases are performed in the facility under intravenous sedation, regional anesthesia, analgesia, or dissociative drugs (excluding Propofol), resulting in moderate/conscious sedation and without the use of endotracheal intubation or laryngeal mask airway, or inhalation general anesthesia. The use of sublingual midazolam, ketamine HCl, and ondansetron (MKO) melt is permitted.

NOTE: Endotracheal tubes and supraglottic airways are permitted in the facility for emergency use only.

Intravenous Sedation may be administered by any of the following:

- Surgeon/proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)
- Registered Nurse (RN) under the direct supervision of a qualified physician

Field and Peripheral Nerve Blocks may be administered by any of the following:

- Physician Anesthesiologist
- Oral and Maxillofacial Surgeon (OMS)
- Dental Anesthesiologist
- Pediatric Dentist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)

Oral or Intranasal Sedation may be administered by any of the following:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Pediatric Dentist
- Oral Maxillofacial Surgeon (OMS)
- Certified Anesthesia Assistant (CAA)
- Certified Registered Nurse Anesthetist (CRNA)
- Registered Nurse under the direct supervision of a qualified physician

The use of propofol, spinal anesthesia, epidural anesthesia, endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.

3. **Class C:** (Facility must meet every Class "A", "B" and "C" requirement)**:**

Surgical and procedural cases may be performed in the facility with intravenous propofol, spinal or epidural, and general anesthesia administered by any of the following:

- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesia Assistant (CAA)

Clarifications:

- Facilities using total intravenous anesthesia (TIVA) and have no inhalational anesthetics present in the facility would not be required to have an anesthesia machine. See standard [Insert new standard number].

ADDITIONAL GUIDANCE

Table 1. ASA Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2019

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) indicates 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) indicates 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. Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* after 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. General Anesthesia is a drug-induced loss of 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.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (Conscious Sedation) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, whereas those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia. (Developed by the American Society of Anesthesiologists: Approved by ASA House of Delegates on October 13, 1999 and last amended on October 15, 2014. Available at: http://www.asahq.org/quality-and-practice-management/practice-guidance-resource-documents/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia. Accessed on August 21, 2017.)

*Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Patient Monitoring – Moderate and Deep Sedation

Many of the complications associated with moderate sedation and analgesia may be avoided if adverse drug responses are detected and treated in a timely manner (i.e., before the development of cardiovascular decompensation or cerebral hypoxia). Patients given sedatives or analgesics in unmonitored settings may be at increased risk of these complications.

Patient monitoring includes strategies for the following: (1) monitoring patient level of consciousness assessed by the response of patients, including spoken responses to commands or other forms of bidirectional communication during procedures performed with moderate sedation/analgesia; (2) monitoring patient ventilation and oxygenation, including ventilatory function, by observation of qualitative clinical signs, capnography, and pulse oximetry; (3) hemodynamic monitoring, including blood pressure, heart rate, and electrocardiography; (4) contemporaneous recording of monitored parameters; and (5) availability/presence of an individual responsible for patient monitoring. See standards in Section 8: Clinical Records, Sub-section H.

SUMMARY TABLE FOR ANESTHESIA OPTIONS

ANESTHESIA OPTIONS	Class A	Class B	Class C
Local Anesthesia	X	X	X
Topical Anesthesia	X	X	X
Nitrous Oxide	X	X	X
Parenteral Sedation		X	X
Field and Peripheral Nerve Blocks		X	X
Dissociative Drugs (excluding Propofol)		X	X
Propofol			X
Epidural Anesthesia			X
Spinal Anesthesia			X
General Anesthesia – with or without endotracheal intubation anesthesia, or laryngeal mask airway (LMA) anesthesia			X

ADDITIONAL GUIDANCE

Nitrous Oxide

Only Nitrous Oxide-Oxygen Delivery Systems with the following safety features may be used in a QUAD A accredited facility:

Alarms - Audio and/or visual alarms (e.g., low- or high-oxygen and nitrous oxide pressure alarms).

Color Coding - Gas tanks, knobs, and hoses are coded by color (standardized nationally, but not necessarily internationally).

Diameter index safety system - A standard for noninterchangeable, removable connections for use with medical gases helps ensure that the appropriate gas flows through the appropriate tubing and cannot be interchanged.

Emergency air inlet - An inlet designed to remain closed as long as gases are being administered to the patient; however, when the oxygen fail-safe system turns the gases off, ambient air is allowed to enter the system so that the patient can continue to breathe through the nasal hood or face mask.

Locks - According to national fire codes, nitrous oxide and other compressed gases must be kept in locked rooms; many manufacturers supply additional locks for the machines at the tanks, the manifold, or the mixer level to prevent staff members from accessing nitrous oxide inappropriately.

Oxygen fail-safe system—The oxygen fail-safe system is designed so that the nitrous oxide supply will be turned off automatically when oxygen delivery is compromised or depleted. Delivery systems are required to provide a minimum oxygen liter flow that ensures 2.5 to 3.0 liters of oxygen per minute is the minimum amount being administered and that concentrations of oxygen never fall below 30% during gas delivery.

Oxygen flush button—This mechanism allows 100% oxygen to be administered through a reservoir bag in the event of an emergency. When the button is pressed, the oxygen flush valve engages, and the system delivers oxygen straight from the pipeline or tank regulator at 45 to 50 psi at a flow rate between 35 and 75 L/min.

Pin-index safety system—Pins protruding from the gas tank yokes have a unique configuration that fits into corresponding holes in the tank valves. This helps prevent the accidental attachment of a nonoxygen tank to the oxygen attachment portal.

Quick connect for positive-pressure oxygen- In an emergency situation in which positive-pressure oxygen is required (e.g., to augment cardiopulmonary resuscitation), quick-connect compatibility helps ensure immediate access to positive-pressure oxygen anywhere in the office.

Reservoir bag—An inflatable rubber reservoir bladder into which fresh gas entering the circuit is conveyed; the bag is filled gradually as gases enter the circuit and deflates with inhalation.

ANESTHESIA REFERENCES

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AANA Scope of Nurse Anesthesia Practice
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Duke Anesthesiology https://www.youtube.com/watch?v=6dnfkEsySKU

Healthline, Conscious Sedation, 2018 https://www.healthline.com/health/conscious-sedation

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https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines%20for%20Safe%20Preparation%20of%20Compounded%20Sterile%20Preperations_%20revised%202016.pdf

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SECTION 1: BASIC MANDATES

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: ANESTHESIA OPTIONS				
1-A-1	The facility practices within the appropriate Anesthesia Class for which it is accredited and in accordance with facility policies and procedures, and industry standards.	A B C	Please see "Anesthesia Definitions" **Interpretive Guidance:** The intent is to ensure the facility practices safely within the anesthetic class for which it is accredited: Class A, B, or C, as outlined in the Anesthesia Class Definitions & Requirements document. **Evaluating Compliance:** • Verify that the surveyor is evaluating the correct facility class and call QUAD A for guidance if the anesthesia option is in question. • Interview surgeons/proceduralists, anesthesia professionals, and nursing staff regarding the types of procedures, surgical cases, anesthesia administered, and the qualifications of staff administering and monitoring the patient for all types of anesthesia. • Review the facility's policy on the required qualifications and training of staff—surgeon/proceduralist, anesthesia professionals (anesthesiologist, CRNA, anesthesia assistant), and RN present when any type of anesthesia is being administered. • Review the surgical log and clinical records to ensure procedures/surgical cases are being	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			conducted consistent with the facility class and authorized clinical staff. • Review personnel files to validate the qualifications and training of staff. **NOTE:** The clinical record review will evaluate only the elements appropriate to the level of anesthesia being provided. **American Association of Nurse Anesthesiology (AANA) Clinical Resources for Practicing CRNAs/Nurse Anesthesiologists** https://www.aana.com/practice/clinical-practice/clinical-practice-resources/ **American Society of Anesthesiologists** https://www.asahq.org/ **ASA Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018** https://pubs.asahq.org/anesthesiology/article/128/3/437/18818/Practice-Guidelines-for-Moderate-Procedural **ASA Continuum of Sedation** https://pubs.asahq.org/view-large/figure/1240051/11tt01.png **Conscious Sedation** https://www.healthline.com/health/conscious-sedation	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			ASA Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018 https://pubs.asahq.org/anesthesiology/article/128/3/437/18818/Practice-Guidelines-for-Moderate-Procedural **American Dental Association (ADA) Guidelines for the Use of Sedation and General Anesthesia by Dentists, 2016** (https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/library/oral-health-topics/ada_sedation_use_guidelines.pdf?rev=b8b34313071d416a99182e8b37add4dd&hash=E5FAB383105610C2988B0ECA2ADBDF95) **Nitrous Oxide, 2023** https://www.ada.org/resources/ada-library/oral-health-topics/nitrous-oxide Can a Dental Assistant Use Nitrous Oxide? https://www.northwestcareercollege.edu/blog/can-a-dental-assistant-use-nitrous-oxide/ **National Library of Congress, Anesthesia for Office-Based Facial Plastic Surgery Procedures, 2023** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10541158/ **Practice Guidelines for Moderate Procedure Sedation and Analgesia by Non-Anesthesiologists, 2018** https://pubs.asahq.org/anesthesiology/article/128/3/437/18818/Practice-Guidelines-for-Moderate-Procedural	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Procedural Sedation 2022 https://www.ncbi.nlm.nih.gov/books/NBK551685/ **Statement of Granting Privileges for Administration of Moderate Sedation to Practitioners 2021** https://www.asahq.org/standards-and-guidelines/statement-of-granting-privileges-for-administration-of-moderate-sedation-to-practitionersv **Statement on Safe Use of Propofol 2019** https://www.asahq.org/standards-and-guidelines/statement-on-safe-use-of-propofol **See Anesthesia Class Definitions & Requirements documents for references.**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-A-2	All care is provided by a credentialed healthcare provider as listed in the Anesthesia Class document and in accordance with facility policies, procedures, and state/provincial and federal law.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: BASIC MANDATES				
1-B-1	The ambulatory surgery center (or other surgical facility) is in compliance with all state laws including State licensure requirements.	416.40 Condition A B C	**Interpretive Guidance:** This standard's intent is that facilities are aware of all state laws and that there is evidence of compliance. **Evaluating Compliance:** • Interview staff to determine knowledge of state laws. • Review personnel files to evaluate compliance. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-B-7	Only recognized abbreviations are allowed to be used in the clinical record.	A B C	**Interpretive Guidance:** The intent for patient safety and documentation consistency is that the facility only uses an approved, recognized list of medical abbreviations for clinical record documentation. The facility must define and approve the abbreviations allowed to be used in the clinical record. **Evaluating Compliance:** • Validate the list of approved abbreviations and resources used, such as MedicineNet Medical Dictionary and Tabers Medical Dictionary, or facility-developed policy. • During clinical record review, note abbreviations used and ensure these are on the official abbreviation list adopted by the facility.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-B-8	The facility must perform a self-survey review of compliance with all QUAD A standards annually prior to the expiration date of its accreditation in each of the two years between QUAD A onsite surveys. The self-survey documentation must be retained for a minimum of 3 years and include: 1. A completed Self-Survey checklist 2. A Plan of Correction for any standard identified as non-compliant 3. Evidence that each plan of correction has been carried out to establish compliance with standards 4. Evidence that findings from the self-survey have been reviewed, included in the facility's Quality Improvement Plan, and discussed in the facility's Quality Improvement meetings.	A B C	**Interpretive Guidance:** The intent is to ensure that the facility performs annual self-surveys consistent with QUAD A requirements. **Evaluating Compliance:** • Review the most recent self-survey for completeness. Are the required elements present? • Are the last 3 years of self-survey documentation available?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: PATIENT SELECTION				
1-C-1	A patient who, by reason of pre-existing or other medical conditions, is at significant risk for outpatient surgery in this facility must be referred to alternative facilities as defined in facility policy. Any surgery for which a patient must be routinely transferred to a hospital after the surgery is not appropriate for an outpatient surgical setting.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure the facility has a defined scheduling policy and procedure that includes only those procedures and a combination of procedures of duration and degree that permit safe recovery and discharge from the facility and identifies patients with significant category risks that should be referred to alternative facilities for care. Services, particularly vascular and ophthalmic procedures, are often no longer offered in a hospital setting. Therefore, vascular and ophthalmic procedures are performed in an outpatient setting for ASA Class IV patients.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Assess facility policy regarding the list of patient risk categories, medical clearance requirements and criteria for accepting or referring patients. • Interview staff about scheduling guidelines and patient risk assessment process. • Is there evidence that procedures are conducted that require routine transfer to a hospital?	
1-C-2	The facility must have a scheduling policy that includes only those procedures and/or a combination of procedures of duration and degree that permit safe recovery and discharge from the facility consistent with state law.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure the facility has a defined scheduling policy and procedure that includes only those procedures and a combination of procedures of duration and degree that permit safe recovery and discharge from the facility and identifies patients with significant category risks that should be referred to alternative facilities for care. QUAD A does not dictate the length of surgery that can be performed in an outpatient setting. The facility must have policies and procedures that outline procedure length and how that time is determined. The general recommendations for safe outpatient surgery involve surgical time limits of four to six hours for a general anesthesia case. If the procedure exceeds this time limit, it may be more	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			appropriate to perform the surgery in a hospital setting. Some states put a time limit on surgery length for the outpatient setting. A facility policy should outline the types of procedures and length of procedures to be performed within the facility. There are several suggestions of times that may be used to define in procedure length in the policy: • Admission to the facility • Time in/time out • Open and close times • Total anesthesia time Whichever definition a facility uses, the patient's recovery time must be considered. The patient's total time in the facility must stay under 23 hours and 59 minutes. In addition, the required staff, including a physician, must be available to monitor the patient's recovery until the patient is discharged from the facility. **Evaluating Compliance:** • Assess the list of patient risk categories, medical clearance requirements and criteria for accepting or referring patients • Review facility policy and interview staff about scheduling guidelines and patient risk assessment process. • Review clinical records.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-C-4	If pediatric services are provided by the facility, there must be a written policy defining the unique perioperative care of pediatric patients. This is based upon considerations of age, BMI or weight, special needs, risk categories, surgery, facility equipment, and capability. The written policy for pediatric patients is available and current.	A B C	**Interpretive Guidance:** The intent of this standard is to determine if there is a written policy that defines the unique perioperative care of pediatric patients based on risk categories, type of surgery, equipment and staff competence and to ensure the safety of children. The policy must also define the age range of pediatric patients served. Pediatric policies should be available for review and up to date. Pediatrics is a multifaceted specialty that encompasses children's physical, psychosocial, developmental and mental health. Pediatric care may begin periconceptionally and continue through gestation, infancy, childhood, adolescence and young adulthood. The American Academy of Pediatrics (AAP) previously identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in the case of a child with special health care needs. The AAP, American Dental Association (ADA), and other organizations no longer support an arbitrary age limit. Although adolescence and young adulthood are recognizable phases of life, an upper age limit is not easily demarcated and varies depending on the individual patient. The establishment of arbitrary age limits on pediatric care by healthcare providers should be	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			discouraged. The decision to continue care with a pediatrician or pediatric medical or surgical subspecialist should be made solely by the patient (and family, when appropriate) and the physician and must take into account the physical and psychosocial needs of the patient and the abilities of the pediatric provider to meet these needs. Pediatric dentistry is an age-defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs. **Evaluating Compliance:** • Review the facility's pediatric services policy. • Interview staff and discuss pediatric patient policy requirements, pediatric ASA risk categories, list of approved pediatric procedures, and current emergency response procedures. • Determine staff competency and training and pediatric equipment/medication availability. Assess emergency pediatric transfer procedures. **American Academy of Pediatrics, Age Limit of Pediatrics, reaffirmed 2023** https://publications.aap.org/pediatrics/article/140/3/e20172151/38333/Age-Limit-of-Pediatrics?autologincheck=redirected	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			American Dental Association, Guidelines for Teaching Pediatric Pain Control and Management, 2021 https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/library/oral-health-topics/ada_guidelines_teaching_pediatric_sedation.pdf?rev=86a7c539ce9d4025bc2b291223f35328&hash=2DF304CA67B8592C2290DE91E816726A **Part 4: Pediatric Basic and Advanced Life Support: 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, 2020** https://www.ahajournals.org/doi/10.1161/CIR.0000000000000901	
1-C-5	No more than 5000 cc's of aspirate should be removed while performing liposuction, unless the patient is monitored overnight within the facility.	B C	**Interpretive Guidance:** The intent is to ensure the safe removal of aspirate. This standard does not allow for the use of a "recovery hotel" for observation. **Evaluating Compliance:** • Interview facility staff to determine whether there have been any cases of liposuction in which more than 5000 cc of aspirate have been removed.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the clinical record for documentation of the amount of aspirate removed and documentation of appropriate overnight monitoring, if applicable. Include at least one liposuction case in the clinical record sample to be reviewed.	
1-C-6	No more than **500cc** of aspirate are permitted to be removed while performing liposuction in a **Class A facility.** The stricter requirement applies if State law differs.	A	**Interpretive Guidance:** The intent is to ensure the safe removal of aspirate In Class A Facilities. This standard does not allow for the use of a "recovery hotel" for observation. **Evaluating Compliance:** • Interview facility staff to determine whether there have been any cases of liposuction in which more than 500 cc of aspirate have been removed. • Review the clinical record for documentation of the amount of aspirate removed and documentation of appropriate overnight monitoring, if applicable. Include at least one liposuction case in the clinical record sample to be reviewed.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: PATIENTS' RIGHTS				
1-D-1	A copy of the QUAD A "Patients' Bill of Rights" is prominently displayed, or a copy is provided to each patient. The QUAD A "Patients' Bill of Rights" is also adhered to by facility personnel.	A B C	**Interpretive Guidance:** The purpose of the Patients' Bill of Rights is to ensure that patients have been advised of their rights and that the basic rules of conduct between patients and caregivers are followed to address access to care, respect, dignity, communication, patient confidentiality and consent for treatments to establish that patients have been advised of their rights. The Patient's Bill of Rights is to be prominently displayed, or a copy of the Patient's Bill of Rights may be given to the patients or provided at the time of registration. Posting the Patient's Bill of Rights on the facility's website alone is not sufficient, Staff must be educated on the facility's policy and procedure regarding the Patient's Bill of Rights upon hire and annually. **Evaluating Compliance:** • Review personnel training documentation to ensure staff have been trained in the Patient Bill of Rights. • Review personnel files. • Observe that the current QUAD A "Patient's Bill of Rights" is prominently displayed in the facility or a copy is provided to each patient. • If copies of the document are provided to each patient, the patient record must reflect this	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			provision. clinical records will be reviewed for evidence of this documentation, if applicable.	
1-D-2	The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.	416.50 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-3	An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section.	416.50(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-4	The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.	416.50(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	Enter observations of non-compliance, comments or notes here.
1-D-5	The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.	416.50(b) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-6	Submission and investigation of grievances. The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.	416.50(d) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-7	The ASC's grievance procedure must ensure that all alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.	416.50(d)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	
1-D-8	The ASC's grievance procedure must ensure that all allegations must be immediately reported to a person in authority in the ASC.	416.50(d)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-9	The ASC's grievance procedure must ensure that only substantiated allegations must be reported to the State authority or the local authority, or both.	416.50(d)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient ☐Not Applicable ☐Corrected Onsite Enter observations of non-compliance, comments or notes here.
1-D-10	The ASC's grievance procedure must ensure that the grievance process must specify timeframes for review of the grievance and the provisions of a response.	416.50(d)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable ☐Corrected Onsite

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	Enter observations of non-compliance, comments or notes here.
1-D-11	The ASC's grievance procedure must ensure that the ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.	416.50(d)(5) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient ☐Not Applicable ☐Corrected Onsite Enter observations of non-compliance, comments or notes here.
1-D-12	The ASC's grievance procedure must ensure that the ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.	416.50(d)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-13	The patient has the right to be free from any act of discrimination or reprisal.	416.50(e)(1) Standard 416.50(e)(1)(i) Standard A B	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
		C	**CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	
1-D-14	The patient has the right to voice grievances regarding treatment or care that is (or fails to be) provided.	416.50(e)(1) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-15	The patient has the right to be fully informed about a treatment or procedure and the expected outcome before it is performed.	416.50(e)(1) (iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-16	If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.	416.50(e)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	
1-D-17	If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.	416.50(e)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-18	The patient has a right to personal privacy.	416.5(f) Standard 416.50(f)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-D-19	The patient has a right to receive care in a safe setting.	416.50(f)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-20	The patient has a right to be free from all forms of abuse or harassment.	416.50(f)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
1-D-21	The patient has a right to refuse treatment.	416.50(g) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: QUAD A-MANDATED REPORTING				
1-E-1	Changes in facility ownership must be reported to the QUAD A Central Office within thirty (30) days of the change.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure facility ownership is current and accurate in the facility's QUAD A file. There should be ownership change information only if the facility's ownership has changed. **Evaluating Compliance:** Interview leadership about any changes to ownership and verify facility ownership with QUAD A records. If there is no evidence that an ownership change has occurred, this standard should be marked as compliant.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
1-E-2	Any change in the physician staff (physician, surgeon/proceduralist and anesthesiologist) must be reported in writing to the QUAD A office within thirty (30) days of the change. Credentials of new physician staff (medical license, evidence of board certification or eligibility, and delineation of privileges for the facility) must also be sent to the QUAD A Central Office within the same timeframe.	A B C	**Interpretive Guidance:** This standard aims to ensure that facility physician staff data is current and accurate in the facility's QUAD A file. Please note that only anesthesiologists who perform procedures (e.g., pain management procedures) are required to be reported under this standard. In addition, this standard does not include contract anesthesiologists. **Evaluating Compliance:** • Verify physician staff listing.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review documentation of notifications to QUAD A. Are changes reported within 30 days?	
1-E-3	Any action affecting the current professional license of any licensed facility staff must be reported in writing to the QUAD A office within ten (10) days of the time the facility becomes aware of such action.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that any adverse professional staff licensure actions are documented and that all clinically licensed staff have a current professional license in good standing. Adverse actions on clinical licenses can include suspension, expiration, probation, etc. **Note:** For RHCs, allied health professionals include certified nurse-midwives, clinical social workers, clinical psychologists, marriage and family therapists, and mental health counselors. **Evaluating Compliance:** • Review with facility leadership the facility's process for identifying and reporting license status changes for the medical director, physicians, pain management staff, and other licensed facility staff. • Review clinical personnel files to determine if there is evidence of such action. • If licensure action has occurred, is there evidence that the action was reported timely to QUAD A?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-E-4	Any death occurring in an accredited facility or any death occurring within thirty (30) days of a procedure performed in an accredited facility must be reported to the QUAD A office within five (5) business days after the facility is notified or otherwise becomes aware of that death. In addition to this notification, the death must be contemporaneously reported as an adverse event in the online Patient Safety Data Reporting portal. In the event of a death occurring within thirty (30) days of a procedure performed in an QUAD A-accredited facility, an unannounced survey may be performed by a senior surveyor.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview the physician and nursing staff regarding any deaths that have occurred since the last survey. • Death records should be incorporated into the clinical record review sample if deaths have occurred. • Request evidence to verify that any deaths were reported to QUAD A within the required timeframes. • Ask the facility to log on to their PSDR portal and ensure any patient death (on the day of or within 30 days of the procedure) has been reported.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION F: PATIENT SAFETY DATA REPORTING				
1-F-1	Online Patient Safety Data Reporting is performed at least every three (3) months in accordance with the due dates established by QUAD A and includes submitting random cases and all adverse events to the QUAD A portal at www.quada.org.	A B C	**Interpretive Guidance:** This intent is to ensure that required facility quarterly reporting to QUAD A on a wide variety of data. Standards apply to every surgical program type. 1-F-1 to 1-F-6 are the Patient Safety Data Reporting standards, referred to as PSDR. This standard requires the facility to report safety data on both random patient cases and also cases that are defined as adverse events. **PSDR Reporting Deadlines** **Period # Cases Performed Reporting Deadline** Period 1 January 1 - March 30 April 15 Period 2 April 1 - June 30 July 15 Period 3 July 1 - September 30 October 15 Period 4 October 1 - December 31 January 15 **Evaluating Compliance:** • Interview the Quality Coordinator to determine the facility's process for documenting, investigating, and reporting adverse events. • Request that the facility pull up their PSDR portal or refer to printed confirmations of PSDR reporting to validate that reports have been submitted on a timely basis or refer to printed confirmations of PSDR reporting	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-F-2	For each surgeon/proceduralist operating in the facility, the random sample of the cases must include, at a minimum, the first case performed by such surgeon/proceduralist each month during the reporting period for a total of three (3) cases. The facility must submit into the online Patient Safety Data Reporting portal a minimum of three (3) cases, or all cases performed by surgeons who have performed fewer than three (3) in the respective period, every three (3) months.	A B C	**Interpretive Guidance:** The intent is to ensure patient safety through PSDR reporting. When a surgeon/proceduralist has performed fewer than three (3) cases during the reporting period, complete the **Patient Safety Data Reporting Exemption Form.** Before submitting this document, make sure to submit all cases online (www.quada.org). **Evaluating Compliance:** • Ask the facility to log in to the PSDR system and open previous periods to demonstrate compliance or refer to printed confirmations of PSDR reporting. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. **PSDR Reporting Exemption Form** https://6276684.fs1.hubspotusercontent-na1.net/hubfs/6276684/PSDR%20Exemption%20Form-2.pdf **Patient Safety Data Reporting Exemption Form** https://6276684.fs1.hubspotusercontent-na1.net/hubfs/6276684/PSDR%20Exemption%20Form-2.pdf	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-F-3	All adverse events that occur within thirty (30) days of any procedure are submitted contemporaneously with the facility learning of the occurrence of such adverse events to the online Patient Safety Data Reporting portal.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. Adverse events must be defined in facility policy and procedures. At a minimum, include those adverse events addressed in Sub-Section E: QUAD A Mandated Reporting and Sub-Section F: Patient Safety Data Reporting and any other adverse events determined by the facility are included, along with severity guidance. **Evaluating Compliance:** • Interview the Quality Coordinator to determine the facility's process to document, investigate and report adverse events • Review Quality data and Governing Body meeting minutes for evidence of adverse events in the past twelve (12) months. Compare cases noted in the facility's documentation to those reported to QUAD A • Review the facility's adverse event documentation and request the facility to provide evidence that the adverse events were reported via the PSDR system.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Ask the facility to log in to the PSDR system and open previous periods to demonstrate compliance. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.770. **National Quality Forum (NQF), Serious Reportable Events** https://www.qualityforum.org/Topics/SREs/Serious_Reportable_Events.aspx **NQF List of Serious Reportable Events,** https://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx	
1-F-4	Reportable adverse events include, but are not limited to: Any unplanned hospital admission	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any unplanned hospital admissions have occurred over the past three (3 years. • Review the facility's adverse event documentation to identify the patient(s). Ask	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			the facility to log in to the PSDR system and open the reported case to demonstrate compliance or refer to printed confirmations of PSDR reporting. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD.	
1-F-5	Reportable adverse events include, but are not limited to: Any emergency room visit	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any emergency room visits have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case to demonstrate compliance or refer to printed confirmations of PSDR reporting.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD.	
1-F-6	Reportable adverse events include, but are not limited to: Any unscheduled return to the operating room for a complication of a previous surgery	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any unscheduled returns to the operating room for complications have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case to demonstrate compliance or refer to printed confirmations of PSDR reporting • If there is any question about whether the facility has submitted the required cases,	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-7	Reportable adverse events include, but are not limited to: Any complications such as infection, bleeding, wound dehiscence, or inadvertent injury to another body structure.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any complications have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case to demonstrate compliance. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
1-F-8	Reportable adverse events include, but are not limited to: Any cardiac or respiratory problems during the patient's stay at the facility or within 48 hours of discharge	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if cardiac or respiratory problems occurred during the patient's admission or within 48 hours of the patient's discharge over the past three (3 years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of the PSDR reporting to demonstrate compliance.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• If there is any question about whether the facility has submitted the required cases contemporaneously with when the facility becomes aware of the event, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-9	Reportable adverse events include, but are not limited to: Any allergic reactions.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any allergic reactions have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance. • If there is any question about whether the facility has submitted the required	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-10	Reportable adverse events include, but are not limited to: Any incorrect needle or sponge count.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. The pre- and post-surgical counts (instrument, sponge, and needle counts) are part of the Surgical Safety Checklist. **Evaluating Compliance:** • Interview facility staff to determine if any incorrect needle or sponge counts have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			refer to printed confirmations of PSDR reporting to demonstrate compliance. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-11	Reportable adverse events include, but are not limited to: Any patient or family complaint	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any patient or family complaints have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-12	Reportable adverse events include, but are not limited to: Any equipment malfunction leading to injury or potential injury to the patient.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any equipment malfunctions leading to injury or potential injury to the patient have occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-13	Reportable adverse events include, but are not limited to: Any death occurring within thirty (30) days of a procedure	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any deaths have occurred over the past three (3) years. • Review the facility's adverse event documentation log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance. • If there is any question as to whether the facility has submitted the required	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			cases, please call the QUAD A office at 224.643.7704. • Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-14	Reportable adverse events include, but are not limited to: Any iatrogenic dental trauma	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that the details of adverse events that occur within thirty (30) days of the procedure are reported to QUAD A within the required timeframes so that the circumstances may be reviewed and investigated when necessary. Adverse events must be reported to QUAD A irrespective of the perceived nature or cause. **Evaluating Compliance:** • Interview facility staff to determine if any iatric dental trauma has occurred over the past three (3) years. • Review the facility's adverse event log to identify the patient(s). • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review clinical records. If any adverse events are identified, verify contemporaneous reporting to QUAD A.	
1-F-15	Each adverse event submission must include: • The identification of the problem, • The immediate treatment or disposition of the case, • The outcome, • The reason for the problem, and • An assessment of the efficacy of treatment.	A B C	**Interpretive Guidance:** The intent is to ensure that adverse events reporting is complete and accurate. **Evaluating Compliance:** • Review adverse events submissions to confirm the required reporting elements are addressed. • Ask the facility to log in to the PSDR system and open the reported case or refer to printed confirmations of PSDR reporting to demonstrate compliance. • If there is any question about whether the facility has submitted the required cases, please call the QUAD A office at 224.643.7704.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 2: FACILITY LAYOUT & ENVIRONMENT

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: LAYOUT				
2-A-1	The Operating Suite is physically and distinctly separate and segregated from the General Office Area (waiting room, exam room(s), administrative area, physician office, staff lounge, etc.)	B C	**Interpretive Guidance:** The intent is to ensure that the surgical suite is contained and separated from other areas to minimize opportunities for infection and cross-contamination. **Evaluating Compliance:** • Conduct a walk-through of the facility to get an understanding of the facility's physical layout. • Is the surgical "suite" distinct and separate from other areas? • Does the layout of the walk-through match the floor plan that the facility submitted? **Facilities Guidelines Institute – Resource** https://www.fgiguidelines.org/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
2-A-2	The Operating Suite includes the Operating Room, Prep/Scrub area, Clean and/or Dirty Room, and Post- Anesthesia Care Unit (PACU).	B C	**Interpretive Guidance:** The intent is to ensure that the Operative Suite includes the required components. Minor procedures may be performed in an exam room, if appropriate based on the procedure and patient status. **Evaluating Compliance:** • Determine if the operating suite includes the required components.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Are minor procedures only performed in an exam room?	
2-A-3	There is a separate and adequately sized Post-Anesthesia Care Unit (PACU) within the operating room suite.	416.44(a)(2) Standard B C	**Interpretive Guidance:** The intent is to ensure that there is a room within the facility where patients recover immediately after surgery. A "room" consists of an area with at least semi-permanent walls from floor to ceiling separating it from other areas of the facility. The size of the recovery room must be commensurate with the number of ORs in the facility and the expected volume of patients who will be in recovery simultaneously. **Evaluating Compliance:** Determine if there is a separate room in which patients recover from their surgery. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-A-7	All major surgery is done in the separate and distinct operating room(s).	A B C	**Interpretive Guidance:** The intent is that major surgeries are performed in a traditional and fully equipped OR. Procedures must be performed in a suitable area. Major surgery is not permitted in a procedure or exam room. Major surgery is an invasive operative procedure where one or more of the following occurs: 1. A body cavity is entered 2. A mesenchymal barrier is crossed 3. A fascial plane is opened 4. An organ is removed 5. Normal anatomy is operatively altered **Evaluating Compliance:** • Review OR log and/or clinical record for documented location of surgeries performed. • Interview key staff about locations where procedures are allowed in the facility.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
2-A-8	Unauthorized individuals are deterred from entering the operating room suite either by locks, alarms, signage, or facility personnel	A B C	**Interpretive Guidance:** The intent is to ensure that unauthorized individuals do not have access to the OR suite. **Evaluating Compliance:** • Review any policies that may exist, limiting the type of personnel and other individuals allowed access to the operating room suite.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Interview staff related to whom is allowed access to the operating suite(s). Inquire about access that staff have to the area, such as housekeeping, clerical staff, etc. Ask about deterrents used to limit access to these areas. • Observe any unauthorized entry into the operating suite area(s). Verify that only those with appropriate credentials can enter. If the facility utilizes locks or alarms, test to ensure they are working appropriately by attempting to gain access to the operating suite. • Observe that appropriate locks, alarms, facility personnel, or signage are posted outside the Operating Suite, notifying individuals that only authorized individuals are allowed past the operating suite doors.	
SUB-SECTION B: FACILITY ENVIRONMENT				
2-B-1	The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.	416.44 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-B-2	The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.	416.44(a) Standard 416.51(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
2-B-3	The entire facility must be maintained, equipped, regularly cleaned, sanitary, and free of clutter and litter, consistent with a medical facility designed to perform procedures.	A B C	**Interpretive Guidance:** All areas of the facility must be clean and sanitary. The facility has policies and procedures in place that address the frequency and type of cleaning and disinfectants required. **Evaluating Compliance:** • During the facility tour, determine if the entire facility is clean and sanitary, maintained.and free of clutter and litter. • Review the facility cleaning policies and procedures. • Interview staff regarding cleaning policies and procedures. **AORN eGUIDELINES, Environmental Cleaning, 2020** https://aornguidelines.org/guidelines/content?sectionid=173715702&view=book#236401528 **APIC Environmental Services** https://apic.org/Resources/Topic-specific-infection-prevention/Environmental-services/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC Environmental Cleaning Procedures Best Practices for Environmental Cleaning in Global Healthcare Facilities with Limited Resources, 2024 https://www.cdc.gov/healthcare-associated-infections/hcp/cleaning-global/procedures.html **CDC Environmental Cleaning Program Improvement Toolkit: A Practical Guide for Implementing the Best Practices for Environmental Cleaning in Healthcare Facilities in Resource-Limited Settings** https://www.cdc.gov/healthcare-associated-infections/media/pdfs/environmental-cleaning-toolkit-guide-508.pdf	
2-B-4	The walls, cabinets, countertops, blinds and shades, and flooring are covered with smooth and easy-to-clean material that is free from tears, breaks, or cracks. If the floors contain seams or individual tiles, they are sealed with an impermeable sealant other than silicone.	A B C	**Interpretive Guidance:** The intent is to minimize areas where contaminants can be left behind after cleaning. Contaminants could create a dirty and unsafe environment. The facility has cleaning policies and procedures in place that address cleaning and maintenance of walls, countertops, blinds and shades, cubicle curtains, and flooring. Cabinets and countertops must be made of non-porous and non-absorbent materials. Laminate, stainless steel, and glass are examples of acceptable materials. Floors in clinical areas (does not apply to the operating room) are made of non-porous and non-absorbent materials. Examples of	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			acceptable materials include luxury vinyl tile, vinyl composite tile, and sheet vinyl. These examples do not apply to the operating room flooring. The Facility Guidelines Institute states that the operating room shall have monolithic (seamless) floor and wall base assemblies and an integral coved wall base that is carried up the wall a minimum of six (6) inches and is tightly sealed to the wall. Flooring must also be non-porous and non-absorbent. Homogenous sheet vinyl and homogenous sheet rubber, are the best options for operating room floors. Sheet format products must have heat-welded seams where the sheets are thermally fused via the use of a vinyl or rubber heat weld applied with a heat weld gun. This is how the sheet becomes monolithic or seamless. Surfaces must be able to be cleaned with a hospital-grade EPA-approved disinfectant. Easy-to-clean carpets may be used in non-clinical areas, including offices, waiting rooms, lobbies, and public corridors. **Evaluating Compliance:** • During the facility tour, observe walls, floors and countertops. Are they smooth and easy to clean? • Note any walls, floors, blinds and shades, cubicle curtains, and countertops that have tears, breaks, or	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			cracks. Are they repaired or replaced when damaged? • Does the flooring have seams? Does the facility provide documentation that the seams have been sealed with an impermeable sealant other than silicone? • Review the facility's cleaning policies and procedures. • Interview staff. **AORN eGUIDELINES, Environmental Cleaning, 2020** https://aornguidelines.org/guidelines/content?sectionid=173715702&view=book#236401528 **APIC Environmental Services** https://apic.org/Resources/Topic-specific-infection-prevention/Environmental-services/ **CDC Environmental Cleaning Procedures Best Practices for Environmental Cleaning in Global Healthcare Facilities with Limited Resources, 2024** https://www.cdc.gov/healthcare-associated-infections/hcp/cleaning-global/procedures.html **CDC Environmental Cleaning Program Improvement Toolkit: A Practical Guide for Implementing the Best Practices for Environmental Cleaning in Healthcare Facilities in Resource-Limited Settings**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.cdc.gov/healthcare-associated-infections/media/pdfs/environmental-cleaning-toolkit-guide-508.pdf **FGI Guidelines, Application Guidance, 2024** https://fgiguidelines.org/wp-content/uploads/2022/06/FGI_determining_appropriate_room_type_2022-06-24.pdf	
2-B-5	The operating room and scrub area ceiling surface or drop-in tiles are smooth, washable, and free of particulate matter that could contaminate the operating room and scrub area**.**	A B C	**Interpretive Guidance:** The intent of this standard is to minimize potential contamination of the OR and sterile field and supplies. Ceiling tiles should be free from dust and other particulate matter. The presence of staining suggests that there is or has been a water issue above the OR. The cause of the staining must be investigated, addressed and ceiling tiles changed to reduce the likelihood of contamination. **Evaluating Compliance:** During the facility tour, observe the ceiling of all operating rooms. Note any particulate matter or staining on the ceiling tiles.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-B-6	All openings to outdoor air are effectively protected against the entrance of insects, animals, etc. The facility must have policies and procedures in place and implemented to address these issues.	A B C	**Interpretive Guidance:** The facility must take precautions to maintain a clean and sanitary environment, free from outside air pollutants, animals and insects. Policies and procedures must be in place and implemented to address these precautions. These activities must be conducted in accordance with professionally recognized standards of infection control practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN). **Evaluating Compliance:** • Interview facility staff to assess which nationally accepted standards of practice have been adopted by the facility. • Observe any evidence of outside air, insects, or animals throughout the facility. This would include gaps in door seals, evidence of insects and rodents. **AORN eGUIDELINES, Environmental Cleaning, 2020**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://aornguidelines.org/guidelines/content?sectionid=173715702&view=book#236401528 **APIC Environmental Services** https://apic.org/Resources/Topic-specific-infection-prevention/Environmental-services/ **CDC Environmental Cleaning Procedures Best Practices for Environmental Cleaning in Global Healthcare Facilities with Limited Resources, 2024** https://www.cdc.gov/healthcare-associated-infections/hcp/cleaning-global/procedures.html **CDC Environmental Cleaning Program Improvement Toolkit: A Practical Guide for Implementing the Best Practices for Environmental Cleaning in Healthcare Facilities in Resource-Limited Settings** https://www.cdc.gov/healthcare-associated-infections/media/pdfs/environmental-cleaning-toolkit-guide-508.pdf	
2-B-19	Smoking is prohibited in the entire facility.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Assess signage prohibiting smoking in the facility. • Observe the practice of staff, patients, and families.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: OPERATING ROOM ENVIRONMENT				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-C-1	Each operating room must be designed and equipped so that the types of operations conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.	416.44(a)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
2-C-2	Each operating room is of a size adequate to allow for the presence of all equipment and personnel necessary for the performance of the operations, and must comply with applicable local, state/provincial or federal/national requirements. There must be ample clear space on each side of the procedure table to accommodate emergency personnel and equipment in case of emergency and permit the safe transfer of the patient to a gurney for transport.	A B C	**Interpretive Guidance:** The intent is to ensure staff and equipment can safely move about in the operating room. If there is a question about maneuverability, facility staff should be able to physically demonstrate that ample space is available to safely transfer a patient during an emergency. The movement of staff and patients on stretchers must proceed safely and uninhibited by obstructions. See 2018 FGI standards for recommended room sizes. **2018 FGI Guidelines** https://www.fgiguidelines.org/wp-content/uploads/2017/11/E94_HCD2017_A_New_Class_Act.pdf **Evaluating Compliance:** • Interview staff to determine if there are specific space requirements for their locality.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Observe ample space is available for maneuvering during the case tracer or observation of care. • Request that the facility staff physically demonstrate that there is sufficient room for staff and equipment to provide safe patient care, including emergency care when needed. **ASHE, Infection Control Guide on Heating and Ventilation and Air Conditioning for Nurse Managers and Clinicians** https://www.ashe.org/system/files/media/file/2022/04/02-Nurse-Manager-Clinicians-Guide_FINAL.pdf **2018 FGI Guidelines** https://www.fgiguidelines.org/wp-content/uploads/2017/11/E94_HCD2017_A_New_Class_Act.pdf	
2-C-3	Each operating room is ventilated and temperature controlled. The facility policy defines parameters based on patient population, procedure, and frequency of monitoring.	A B C	**Interpretive Guidance:** Temperature, humidity, and airflow in ORs must be maintained within acceptable industry standards to inhibit microbial growth, reduce the risk of infection, control odor, and promote patient and staff comfort. Logs should be maintained to show that temperature/humidity readings are regularly monitored. Records should describe the facility's corrective actions when they fall outside of acceptable ranges. **Minimum industry standards**:	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Humidity maintained between 20%-60% (ASHRE, standard 170), Ventilation:15-20 air exchanges per hour (FGI), and Temperature 68-75° F (AORN). **Evaluating Compliance:** • Review facility policy. • Review temperature, humidity, and ventilation logs to determine if appropriate parameters are maintained. • If documented readings are not within parameters, interview staff on what interventions were. implemented to address low or high measurements. • Review reports of air exchanges and confirm air exchanges are compliant. **ASHE, Infection Control Guide on Heating and Ventilation and Air Conditioning for Nurse Managers and Clinicians** https://www.ashe.org/system/files/media/file/2022/04/02-Nurse-Manager-Clinicians-Guide_FINAL.pdf **2018 FGI Guidelines** https://www.fgiguidelines.org/wp-content/uploads/2017/11/E94_HCD2017_A_New_Class_Act.pdf	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-C-4	The facility must have policies and procedures in place that address operating room cleaning, frequency and type of disinfectants used in accordance with industry standards.	A B C	**Interpretive Guidance:** The facility should have a cleaning schedule and policy in place for the Operating Room(s) in accordance with industry standards. **Evaluating Compliance:** • During the facility tour, observe the OR(s) for cleanliness, maintenance, litter and clutter. • Review the facility's cleaning policy and any cleaning logs that are maintained as evidence of compliance with the facility policy. • Interview appropriate staff related to how the OR(s) are cleaned and maintained at the start and end of the day and before/after each procedure. **Appendix B2 Specialized Patient Areas | Environmental Cleaning in Global Healthcare Settings| HAI |** https://www.cdc.gov/healthcare-associated-infections/hcp/cleaning-global/appendix-b2.html?CDC_AAref_Val=https://www.cdc.gov/hai/prevent/resource-limited/special-areas.html **AORN, Environmental Cleaning, 2020** https://aornguidelines.org/guidelines/content?sectionid=173715702&view=book	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-C-5	There is adequate storage space within the operating room to hold equipment, supplies and medications. Unused equipment, supplies and medications are covered to avoid contamination.	A B C	**Interpretive Guidance:** The intent of the standard is to ensure adequate storage in the operating room to avoid contamination and minimize the need for staff to leave the operating room for frequently used supplies, equipment and medications. Equipment is stored out of the way. Unused equipment, supplies, and medications are covered (in cabinets, drawers, bins, or dust covers are used) if kept in the operating room to avoid contamination. **Evaluating Compliance:** • Observe operating room storage space. • Interview staff regarding the adequacy of storage space and the frequency at which staff must leave the operating room for frequently used supplies, equipment, and medications. • Are unused equipment and supplies covered or kept in a defined storage area? • Are unused and medications kept in a cabinet?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-C-6	If a pre-existing sink is present in an operating room for other than endoscopic, urological, or case-by-case basis use, the water source must be disabled and the sink must be removed during any future construction project.	B C	**Interpretive Guidance:** The intent of the standard is to minimize infection control cross contamination. **Evaluating Compliance:** • Review facility policy related to the use of the sink located in the OR. • Interview staff to determine when the sink is used and to determine compliance.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-C-9	The operating room(s) are temperature controlled between 22.2 degrees Celsius (68-72 degrees Fahrenheit) and relative humidity is between 20-60%.	B C	**Interpretive Guidance:** Each operating room should have a separate temperature control. For the established temperature range in operating rooms, **NFPA 99-2012 requires ASHRAE 170-2008, Ventilation Table 7-1.** • For operating rooms in **classes B and C**, the established range for temperatures is 20 – 22.2 degrees Celsius / 68 to 72 degrees Fahrenheit. • **Class A** operating/procedure rooms should have a range of 21.1 – 23.9 degrees Celsius / 70 to 75 degrees Fahrenheit. • Ventilation Table 7-1 includes an exception for temperatures to be outside of established minimum ranges when required for patient comfort and/or medical conditions. If a provider uses this exception and follows established policy, logging the issue is not required. • The relative humidity should be between 20% and 60%. If the temperature falls below the established range, verify that it will not have a negative impact on patient care or the relative humidity level or take further action. If the temperature/humidity falls outside the acceptable range, corrective action will be taken and remeasurement to confirm temperature and humidity	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			within the acceptable range prior to the start of surgical procedures. **Evaluating Compliance:** • Review logs kept to monitor temperature and humidity recordkeeping and the description of corrective action as applicable. • Confirm corrective action is taken if temperature and/or humidity are outside the acceptable range and remeasurement to confirm that corrective action was effective in bringing temperature/humidity back into an acceptable range. • Interview staff regarding the steps to be taken when the temperature exceeds the acceptable range. **ASHRAE/ASHE standard 170-2008 – Ventilation of Health Care Facilities. Table 7.1** www.ashrae.org/File%20Library/Technical%20Resources/Standards%20and%20Guidelines/Standards%20Addenda/170-2008/ad170_2008_d.pdf **AORN Infection Control Guide on Heating, Ventilation and Air Conditioning (HVAC)** https://prod.ashe.org/system/files/media/file/2022/04/02-Nurse-Manager-Clinicians-Guide_FINAL.pdf	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: POST-ANESTHESIA CARE UNIT (PACU) ENVIRONMENT				
2-D-1	The PACU is maintained, clean and free of litter.	B C	**Interpretive Guidance:** The intent of this standard is to ensure the PACU is maintained, clean, and free of litter. The facility must maintain a functional and sanitary environment to avoid sources and transmission of infections and communicable diseases. Clean and free of litter includes but is not limited to free of dust and visible soil; walls are smooth, uniform, and easy to clean without chips/cracks in wall finish; no mold or rust in the facility; HVAC and plumbing are in working order; windows and door frames are in working order; no visible damage or disrepair of electrical receptacles and light switches evident. **Evaluating Compliance:** • During the tour of the facility, note the general appearance of cleanliness and odors. • Observe floors, horizontal surfaces and walls for intactness and ease of cleaning and disinfecting. • Interview staff to determine whether cleaning/disinfection takes place at the appropriate frequencies, using suitable EPA-registered agents. Ask for supporting documentation to confirm. • Determine how hazardous materials are disposed of, and whether general trash is disposed of properly.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the techniques for cleaning and disinfecting environmental surfaces, disposal of regulated and non-regulated waste, and pest control. **Common Rust Issues in Healthcare Facilities and How to Deal with Them, 2024** https://thedailynotes.com/rust-issues-healthcare-facilities-deal **RUST: The Silent Threat to Infection Control, 2022** https://blog.cmecorp.com/rust-the-silent-threat-to-infection-control	
SUB-SECTION E: STORAGE				
2-E-1	Sterile supplies and equipment are stored away from potential contamination in closed cabinets/drawers; or if not, sterile supplies must be stored away from heavy traffic areas and potential contamination hazards.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure that sterile supplies and equipment are stored in a safe and appropriate manner to maintain cleanliness, sterility, functionality, easy access, and identification and to avoid contamination and injury, maintaining a safe environment for patients and staff. Sterile supplies stored anywhere in the facility should be protected from dust, damage to the packaging, moisture, pests, temperature/humidity exceeding recommended ranges, etc. The facility must provide and maintain a sanitary environment to avoid the sources and transmission of infections and communicable diseases. All areas of the facility must be clean and sanitary.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Corrugated cardboard presents an infection control issue. It is susceptible to moisture, water, insects, vermin, and bacteria in warehousing, storage, and transportation environments. Supplies and equipment are generally delivered in corrugated cardboard boxes. Once the supplies and equipment have been removed, the boxes are removed from the facility. They should never be present near semi-sterile or sterile areas. **Evaluating Compliance:** • Observe the facility for overall cleanliness and maintenance and organization of storage areas. • Observe to determine if supplies and equipment are stored safely to maintain their cleanliness or sterility, functionality, and prevent injury to patients and staff. • Observe to determine if sterile supplies and equipment are stored off the floor. • Observe to determine if sterile supplies are stored away from potential contamination in closed cabinets, drawers, shelves or otherwise stored to avoid potential hazards and contamination. • Observe under the sink cabinets to ensure no patient equipment or surgical supplies are stored in this area. If storage is maintained under the sink, a risk assessment must be completed by	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			the facility to ensure products will not be damaged in the event of a sink plumbing leak or moisture in this environment. • Observe the facility to ensure that corrugated cardboard boxes are not stored within clean or sterile supply areas. **Healthcare Facilities Today, Q&A: Corrugated cardboard boxes** https://www.healthcarefacilitiestoday.com/posts/QA-Corrugated-cardboard-boxes--13520	
2-E-2	Storage space for sterile supplies and equipment is organized in a manner that maintains cleanliness, sterility, and functionality, provides easy access for identification, and minimizes the risk of contamination and injury to patients and staff.	A B C	**Interpretive Guidance:** The intent is that the risk of contamination and injury to patients and staff is minimized. Medical supplies and equipment are visible, accessible, and organized in a clean environment for improved workflow and inventory management. Only areas/rooms designated for storage are used in the facility unless the facility has FDA documentation permitting use for storage. Corridors are kept clear to facilitate the free and safe movement of staff, patients, and equipment. Patient care supplies are stored away from the edge of a sink to avoid possible splash contamination. They are also not stored near water sources to avoid possible splash	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			contamination or excessive moisture, which may compromise packaging. Per the National Fire Protection Association (NFPA) Life Safety Code 101, storage must maintain an 18-inch clearance from the ceiling to allow for proper function of the fire and safety sprinkler system; however, shelving secured to the wall may go all the way to the ceiling, encroaching into the zone within 18 inches of the ceiling provided that the shelving is more than 18 inches laterally away from any sprinkler heads. The NFPA 13 2022 10.2.8.1 (*) guideline 10.2.8.2. states: *The 18 in. (450 mm) dimension shall not limit the height of shelving on a wall or shelving against a wall in accordance with 10.2.8.1.* The NFPA 13 guideline 10.2.8.2.1 guideline states: *Where shelving is installed on a wall and is not directly below sprinklers, the shelves, including storage thereon, shall be permitted to extend above the level of a plane located 18 in. (450 mm) below ceiling sprinkler deflectors* along with guideline 10.2.8.2.2 stating: *Shelving, and any storage thereon, directly below the sprinklers shall not extend above a plane located 18 in. (450 mm) below the ceiling sprinkler deflectors.* If used, fixed, or mobile-wired shelving, the lowest level shelf is covered with a plastic cover. **Evaluating Compliance:**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Observe areas used for storage to confirm the area was designed for storage (away from possible contamination sources, maintain cleanliness and sterility of supplies as applicable). • Are corridors kept clear to provide for the safe movement of staff, patients, and equipment? • Are patient care supplies maintained away from sinks to avoid possible splash contamination? • Is there an 18-inch clearance between the deflector and the top of storage? • If used, fixed or mobile-wired shelving is the lowest shelf covered with a plastic cover? **The 18-inch Supply Storage Guideline in Sterile Processing** https://www.evolvedsterileprocessing.com/post/one-misunderstood-supply-storage-guideline-the-18-inch-ceiling-limit **2012 edition, NFPA 101 LSC** https://www.nfpa.org/codes-and-standards/nfpa-101-standard-development/101	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
2-E-3	As applicable to the setting, outdated medical supplies, instruments, implants, and equipment are removed and destroyed in accordance with federal/national, state, provincial, and local regulations.	A B C	**Interpretive Guidance:** No outdated medical supplies, instruments, implants, or equipment are used in the provision of patient care. Outdated supplies, instruments, implants, or equipment may not maintain their sterility or integrity. Medical supplies, instruments, implants and equipment not stored within proper temperature settings may be considered expired for patient use. Some may require certain temperatures to maintain potency. Sterile items that can be reprocessed a specific number of times (e.g., LMA and implant sizers) per the manufacturer's instructions for use must have documentation regarding the number of times the item has been processed. Re-processing "expired" supplies is not acceptable unless the item is implicitly approved for such and the process is documented in the manufacturer's IFU. When the item does not come with cleaning and re-sterilization instructions, it must be considered a single-use item with a terminal expiration date. **Evaluating Compliance:** • Inspect and check for expired supplies, instruments, implants, and equipment used in the facility.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Check manufacturers' recommendations for accurate best use by date or expirations. • If expired supplies, instruments, implants, or equipment are observed, interview staff to determine if a procedure is in place to check expiration dates on a regular basis. • Are sterile items that can be reprocessed a specific number of times, reprocessed in accordance with the manufacturer's instructions for use? Is documentation present regarding the number of times the item has been reprocessed? • Interview staff.	

SECTION 3: SAFETY

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: General Safety				
3-A-1	The Facility must comply with all applicable Occupational Safety and Health Administration (OSHA), Centers for Disease Control and Prevention (CDC), National Fire Protection Association (NFPA), federal, state and local codes and regulations. The facility must comply with the applicable stricter regulation (whether it is the QUAD A Standard or local, state, or federal law).	A B C	**Interpretive Guidance:** QUAD A is committed to establishing minimum guidelines to provide safe and effective outpatient procedure care. The intent is to provide facilities with a solid foundation of nationally recognized resources as minimal guidelines for general safety and patient safety to guide facility policies and procedures.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Interview staff to verify that facility policies and procedures are created using nationally recognized guidelines. • Verify that the facility has posted OSHA Publication 3165 or the state plan equivalent stating workers' rights to a safe workplace and how to file a complaint. **OSHA Publication 3165, Job Safety and Health: It's the Law Workplace Poster -** https://www.osha.gov/publications/poster **Centers for Disease Control and Prevention (CDC)** https://www.Cdc.gov **National Fire Protection Association (NFPA)** https://www.nfpa.org/for-professionals/codes-and-standards/list-of-codes-and-standards/free-access	
SUB-SECTION B: Facility Safety Manual				
3-B-1	There is a Facility Safety Manual that is reviewed and updated annually and is in accordance with all other federal/national, provincial, state and local regulations. For international facilities, there must be evidence that specific national, provincial and local regulations are included.	A B C	**Interpretive Guidance:** The Facility Safety Manual is a compilation of safety procedures and guidelines to follow in emergencies or unsafe situations. The safety manual includes guidelines to prevent injury and illness of staff, patients and visitors. Staff	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			are knowledgeable of the location and contents of the Facility Safety Manual. **Evaluating Compliance:** • Review the Facility Safety Manual. • Look for documented evidence that the Facility Safety Manual has been reviewed and updated annually. • Interview staff to assess awareness of the Facility Safety Manual, where it is located and its contents. **Outpatient Surgery Cultivate a Culture of Safety, 2024** https://digital.outpatientsurgery.net/view/571733896/4/ **Outpatient Surgery The Essential Elements of a Staff Safety Program, 2024** https://digital.outpatientsurgery.net/view/571733896/14/	
3-B-2	The Facility Safety Manual contains all applicable requirements of OSHA, such as: ➢ Hazzard Communication ➢ Bloodborne Pathogen ➢ Universal Precautions ➢ Ionizing Radiation (if x-ray is present at the facility) ➢ Exit Routes ➢ Electrical Standard	A B C	**Interpretive Guidance:** The intent is to ensure safe and healthy working conditions for workers as required by OSHA and minimize injuries and hazards. The facility safety manual should address all of the topics listed in the standard unless the facility documents in the manual that specific items have been exempted based on the facility, procedures performed, and patient population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
	➢ Emergency Actions in the event of fire or other emergencies ➢ Exposure Control Plan ➢ Fire Safety ➢ Medical and First Aid dependent upon workplace circumstances ➢ Personal Protective Equipment (PPE) ➢ Ergonomic Hazards ➢ Workplace Violence ➢ Slips, Trips, and Falls ➢ Influenza ➢ Tuberculosis ➢ Emergency Response ➢ Chemical Hazards ➢ Other hazards such as Compressed Gas, Laser Hazards, Latex Allergy		Staff training is documented in the personnel file. See Section 11: Personnel, Sub-Section I: Personnel Training. **OSHA General Duty Clause** Each employer -- (1) shall furnish to each of its employees a place of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees; (2) shall comply with occupational safety and health standards promulgated under this Act. (b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his/her own actions and conduct. Per CDC "Tuberculosis (TB) screening and testing of health care personnel is recommended as part of a TB Infection Control Plan and might be required by state regulations. For TB regulations in the facility's state, contact the state or local TB control program. **Evaluating Compliance:** • Review the Facility Safety Manual for inclusion of all required elements. • Interview staff on how employees are educated annually and when the Facility Safety Manual is updated.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Verify in the personnel files that documentation is present for education on the Facility Safety Manual upon hire, with any significant updates, and annually. **OSHA Compliance Quick Start** https://www.osha.gov/complianceassistance/quickstarts/health-care **OSHA A to Z** https://www.osha.gov/a-z#l **OSHA Healthcare** https://www.osha.gov/healthcare **OSHA Quick Reference Guide to the Bloodborne Pathogens Standard** https://www.osha.gov/bloodborne-pathogens/quick-reference **CDC Tuberculosis** https://www.cdc.gov/tb/index.html	
SUB-SECTION C: Hazardous Agents				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-C-1	All explosive and combustible materials and supplies are stored and handled in a safe manner with appropriate ventilation according to state, provincial, local, and national laws and regulations and/or National Fire Protection Association (NFPA) codes and OSHA regulations.	A B C	**Interpretive Guidance:** The intent is that the facility stores and handles explosive and combustible materials, with appropriate ventilation, in a safe and regulated manner to protect the safety of facility patients, visitors, staff, and the surrounding community. **Evaluating Compliance:** • During the facility tour, observe the physical storage and handling of explosive and combustible materials (e.g., chemicals, medical gases) and ensure ventilation spaces or extraction devices are used in accordance with regulations or the manufacturer's IFU. • Interview staff on storage and handling procedures of explosive and combustible materials. • Are areas ventilated per state/provincial, local or national laws and regulations? • Are combustible materials stored away from fire ignition sources? **International Code Council (ICC) 2018, Compressed Gases** https://codes.iccsafe.org/content/IFC2018/chapter-53-compressed-gases **ICC, 2018, Flammable and Combustible Liquids**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://codes.iccsafe.org/content/IFC2018/chapter-57-flammable-and-combustible-liquids **NFPA 30 Flammable and Combustible Liquids Code, 2021** https://standards.globalspec.com/std/14328537/nfpa-30 **OSHA Compliance Quick Start** https://www.osha.gov/complianceassistance/quickstarts/health-care **OSHA A to Z** https://www.osha.gov/a-z#l **OSHA Healthcare** https://www.osha.gov/healthcare	
3-C-3	Compressed gas cylinders are stored and handled according to state, provincial, local and national laws and regulations, and/or National Fire Protection Association (NFPA) codes.	A B C	**Interpretive Guidance:** The intent is the facility stores and handles compressed gas cylinders in a safe and regulated manner to protect the safety of facility patients, visitors, staff and the surrounding community. **Potential hazards** Depending on the product contained within the cylinder, compressed gases are capable of creating environments that are reactive, explosive, flammable, oxidizing, oxygen-deficient, extremely cold, corrosive or otherwise hazardous to health. Therefore, it's essential to wear the appropriate Personal Protective Equipment (PPE) when	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			handling cylinders and compressed gases. All appropriate firefighting, staff safety and first aid equipment should be available in case of emergencies. **Storage area basics** • Always separate gases by type and keep them in assigned, clearly identified locations. • OSHA requires that cylinders containing flammable gases are either stored at least 20 feet (6.1 meters) away from cylinders containing oxygen and other oxidants or are separated by a fire-resistant wall with a rating of at least 30 minutes that interrupts line of sight. • Poisonous and toxic gases should also be stored separately. • Do not store cylinders (empty or otherwise) in hand trucks or cylinder carts. **Storage area conditions** • Gas cylinders should only be stored in areas that are well-ventilated and properly illuminated. • Compressed gas storage areas should be identified using proper signage and located away from sources of excess heat, open flame or ignition, and electrical circuits. They should not be located in enclosed or subsurface areas. • Vent hoods are not a safe storage area except for when a cylinder is in use **Securing cylinders in storage**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• The risk of a cylinder falling over and possibly shearing off its valve demands that it always be held in place with a chain or another type of fastener, such as a bench or wall clamp. • While in storage, cylinders without permanently configured valve protection MUST have cylinder valve protection caps firmly in place. **Temperature exposure** • Compressed gas cylinders typically come in two (2) types of materials: steel and aluminum. ➢ Steel cylinders are generally used for more corrosive products. While they are more durable than aluminum cylinders, they should not be stored near steam pipelines or exposed to direct sunlight. ➢ Aluminum cylinders are used to increase the stability of gas mixtures containing specific components. They can be damaged by exposure to temperatures in excess of 350°F (177°C). • No matter the material, extreme temperatures weaken cylinder walls and may result in a rupture. Do not permit cylinder temperatures to exceed 125°F (52°C) or apply devices that will heat any part of the cylinder above this temperature. **Storing and returning empty cylinders** • The cylinder storage area should be arranged so older stock is used first. Remember, cylinder	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			carts and hand trucks are not suitable storage places for any cylinder. • Empty cylinders should be stored separately, clearly identified and promptly returned. When storing depleted cylinders, leave some pressure to prevent backflow that would allow moisture and other contaminants into the cylinder. Ensure that all valves are closed and cylinder caps and/ or guards are securely installed. **Handling compressed gas cylinders** • Most gas cylinders are very heavy and remain empty or filled, as their contents are in gaseous form and weigh very little. Even "empty" cylinders are considered hazardous and are still regulated by the Department of Transportation due to the small amount of residual gas they contain. • The safest way to move cylinders is using a hand truck or cylinder cart specifically designed for this purpose. • Avoid lifting cylinders by their caps or guards or with lifting magnets or slings which can damage the valve. **Before using cylinders** • Before using a cylinder, check to make sure it is properly labeled. Do not accept or use cylinders without a clearly identifiable label. • After ensuring the cylinder is labeled correctly, it's important to read and understand the accompanying Safety Data Sheet (SDS) for	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			detailed technical and regulatory information on the product. • Always remember to wear the appropriate Personal Protective Equipment (PPE) when using cylinders. Depending on the gas, this may include respirators, eyewear, gloves and specialized clothing. • Ensure that equipment such as fire extinguishers, eyewash stations and showers are located nearby and properly maintained, where required. In addition, ambient air monitors with alarms that detect gas are essential safety devices, especially when dealing with highly toxic gases. **Securing cylinders before and after use** • Whenever a cylinder is in use, it must be properly secured with a fastening device. Floor or wall brackets are ideal for cylinders that are stationary and will not be moved while in use. • For cylinders that must be moved around, it's recommended to secure them with portable bench brackets. **Valve outlet connections and fittings** • Before using compressed gas cylinders, it's essential to check that all fittings and connection threads meet properly. Never force them or turn threads the wrong way, as this can cause damage and produce metal particles that might get caught in the poppet. Additionally, do	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			not cross-thread or use adapters between non-mating equipment and cylinders. • Most valve outlet connections are designed with metal-to-metal seals; only use washers where indicated. Never use pipe dope on pipe threads, and do not use Teflon® tape on valve threads to prevent leaking as it may become powdered and get caught on the regulator poppet, causing full pressure downstream. • A regulator should be dedicated to a single valve connection, even if it is designed for different gases. • Check that the gas regulator is compatible with the gas type being used and rated for the appropriate cylinder pressure. • It is important to inspect, maintain and replace pressure equipment regularly. **Evaluating Compliance:** • Review facility policy on storage and use of Oxygen Tanks and other compressed gas cylinders. • During the facility tour observe the storage of medical gases to determine if: ➢ Portable cylinders are secured appropriately when attached to medical equipment or secured with a mechanism (i.e., chain, strap, cart, or crate) to prevent accidental tipping. ➢ Cylinders are labeled “full” or “empty”	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			➢ Cylinders are labeled and classified correctly – the label identifies the gas contained in the tank. The tank label indicates the classification, e.g., flammable, explosive, compressed gases, health hazard, poison, etc. ➢ Oxygen cylinders that are in use are attached to a cylinder stand or to medical equipment designed to receive and hold the cylinder. ➢ Signs are posted making patients, visitors, and staff aware that Oxygen is in Use and that No Smoking is allowed. • Interview staff. Do they know how to safely store, handle, store and transport gases?. • Observe practice, when possible.	
3-C-5	Hazardous chemicals are labeled as hazardous. Any hazardous material removed from the manufacturer's container and placed in a secondary container must be properly labeled.	A B C	**Interpretive Guidance:** The intent is the facility identifies and documents all hazardous materials used, stored, or generated throughout the facility and ensures that they are properly labeled. This index of hazardous materials is updated on an annual basis. This index may be an index of Safety Data Sheets (SDS) maintained for each hazardous product. Hazardous materials that must be included in the inventory are those whose storage, use, or handling are regulated by standards or laws. The SDSs are maintained in an area that is always available to the staff for every hazardous material with which they may come in contact, The SDSs must be readily and quickly	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			available to staff. Hazardous products are appropriately labeled according to regulations and NFPA standards. **Evaluating Compliance:** • Check hazardous materials during the facility tour looking for proper labeling, use, disposal, and storage. • Ask staff to provide SDSs for random selected materials. • Ask staff to see the SDSs to verify that there is an index of SDS for all hazardous materials. • Confirm that the index of hazardous materials is updated annually. • Ask to see the Chemical Hazard Communication Plan. • Verify that the Chemical Hazard Communication Plan is updated annually • Verify that the Chemical Hazard Communication Plan includes the index of chemicals present in the facility. If a chemical is placed into a secondary container (not the one from the manufacturer), it requires an OSHA-approved labeling method such as this: https://www.osha.gov/sites/default/files/publications/OSHA3492QuickCardLabel.pdf	
SUB-SECTION D: Medical Hazardous Waste				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-D-1	All medical hazardous wastes (including disposable sharp items) are disposed of in sealed, labeled containers and stored in compliance with local, state/provincial, and national guidelines, and/or OSHA (Occupational Safety and Health Act) acceptable containers and separated from general refuse for special collection and handling.	A B C	**Interpretive Guidance:** The intent is to ensure safe practices when handling medical hazardous waste**.** **Evaluating Compliance:** • Review facility policies and procedures. • Interview staff. • Observe staff handling medical hazardous waste. **CDC Regulated Medical Waste, 2003** https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste. **EPA Medical Waste, 2024** https://www.epa.gov/rcra/medical-waste **OSHA Hazardous Waste** https://www.osha.gov/hazardous-waste/standards	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
3-D-4	Used disposable sharp items are placed in secure puncture-resistant containers that are located as close to the use area as is practical.	A B C	**Interpretive Guidance:** The intent is to employ safety practices to prevent needlestick injuries and the transmission of HIV, hepatitis A and B, and other bloodborne pathogens. Containers for disposing of used sharps should be based on the following National Institute for Occupational Safety and Health (NIOSH) criteria:	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• **Functionality:** Containers should be puncture-resistant, durable during installation and transport, and an appropriate size and shape. The closure should be secure and minimize exposure during closure. • **Accessibility:** Containers should be upright and easy to operate while preventing the contents from spilling. The container should be placed in a visible location, within easy horizontal reach, and below eye level. The container should also be placed away from any obstructed areas, such as near doors, under sinks, near light switches, etc. • **Visibility:** Containers should be clearly visible to the healthcare worker. The container should be designed so that workers may be able to easily determine the container's fill status and distinguish any warning labels. • **Accommodation:** Containers should facilitate ease of storage and assembly, require minimal worker training, be easy to operate, and have a flexible design. They should also easily accommodate one-handed disposal of a sharps device. Product design should minimize sharp surfaces and cross-infection hazards. Installation and mounting systems	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			should be safe, durable, stable, and cleanable. FDA-cleared sharps containers must be made of heavy-duty plastic, feature a tight-fitting, puncture-resistant lid, remain upright and stable during use, be leak-resistant, and be properly labeled with a hazardous waste warning. Additionally, sharps disposal containers should be disposed of when they are three-quarters full. Information regarding the mounting of sharps containers is based on general safety practices and recommendations from the FDA and OSHA guidelines. While there is no explicit regulation stating that sharps containers must be mounted, it is recommended to place them in stable and secure locations to prevent spills and ensure ease of access. Mounting is one way to achieve this stability and accessibility. If a large sharps container is on the floor, it must be secured to prevent accidental tipping. Sharp containers cannot be on wheels for the same reason. Sharps should not protrude out of the disposal container. Sharps containers should be changed out when they are three-quarters full to prevent overfilling, as recommended by the FDA. This helps avoid spills and reduces the risk of needlestick injuries.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			The Department of Transportation (DOT) has regulations concerning sharps disposal, particularly for containers transported off-site for disposal. These containers must be puncture-resistant and securely closeable to prevent leaks. For sharps containers to be eligible for reuse, they must meet stringent requirements: they must be FDA-approved as reusable medical devices, permanently marked to indicate their suitability as reusable containers, and disinfected effectively based on the type of infectious substance they previously contained. **Evaluating Compliance:** • Review facility policy and procedures on the disposal of used sharps. • Are sharps disposal containers puncture-proof? • Are sharps disposal containers secured to prevent accidental tipping of the container? • Observe employees discarding used sharps. • Observe the placement of sharp containers. (i.e., Are they located close to the use of sharps? Are they placed at the appropriate height level (height of 52-56 inches?) • Are used sharps disposed of properly?	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC - Bloodborne Infectious Diseases - Stop Sticks : Sharps Disposal - NORA Workplace Safety and Health Topic **FDA Sharps Disposal Containers** https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers **Department of Transportation (DOT) Regulations** https://www.hercenter.org/regsandstandards/dot.php **NIOSH - Selecting, Evaluating, and Using Sharps Disposal Containers** https://stacks.cdc.gov/view/cdc/6386 **USDA - Safely Using Sharps** https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers **Sharps Contain Regulations: Your Guide, 2024** https://www.danielshealth.com/knowledge-center/sharps-container-regulations-your-guide	
SUB-SECTION G: Personnel Safety				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-G-1	If an ethylene oxide gas sterilizer or automated endoscope re-processor (AER) is used, appropriate personnel are badge- tested to ensure that there is no significant ethylene oxide or glutaraldehyde exposure.	A B C	**Interpretive Guidance:** Ethylene Oxide (EtO) is a colorless gas that is known to be an eye, skin, and respiratory irritant in low concentrations, as well as presenting carcinogenic, mutagenic, reproductive, and neurologic hazards to workers. The odor of EtO cannot be detected below 700 ppm. Personal monitoring involves measuring a person's exposure to EtO by testing the air that the person (an employee) would breathe regardless of where the person moves in the workplace. A sampling device is attached to the shirt collar or as close as practical to the nose and mouth of the employee in the employee's "breathing zone" – the hemisphere forward of the shoulders with a radius of approximately six to nine inches – to test airborne EtO concentrations. After the samples have been analyzed, the employer must post monitoring results within 15 days of receiving them or notify employees of the results in writing. The employer must also mention the steps being taken to reduce employee exposure when the monitoring results indicate that the time-weighted average or excursion limit has been exceeded. Glutaraldehyde is widely used as a cold sterilant to disinfect heat-sensitive instruments, such as endoscopes, bronchoscopes, and dialysis equipment (NIOSH, 2001). Glutaraldehyde's properties as a chemical sterilant were initially	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			recognized in the early 1960s as the health care industry searched for a safer alternative to formaldehyde, which is regulated by OSHA as a carcinogen (29 CFR 1910.1048). In the years since its introduction as a disinfectant/sterilant, glutaraldehyde has been linked with a variety of health effects – ranging from mild to severe – including asthma, breathing difficulties, respiratory irritation, and skin rashes. (Pryor, 1984; Crandall, 1987). The Federal Occupational Safety and Health Administration (OSHA) does not have a Permissible Exposure Limit for glutaraldehyde. The National Institute for Occupational Safety and Health (NIOSH) established a Recommended Exposure Limit (REL) of 0.2 ppm in 1989 (http://www.cdc.gov/niosh/npg/npgd0301.html). Other organizations that have occupational exposure limits include the American Conference of Governmental Industrial Hygienists (ACGIH), which currently recommends a Threshold Limit Value (TLV) of 0.05 ppm in air, measured as a ceiling concentration, and the United Kingdom Health and Safety Executive which also has established a 0.05 ppm Workplace Exposure Limit (WEL) averaged over both 8 hours and 15 minutes. The occupational exposure limits discussed above were current at the time this document was published. However, it is essential that health care personnel keep informed of current Federal, state, and local regulations applicable to glutaraldehyde, and professional guidelines.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • During the facility tour, observe the use of EtO in the facility. • If EtO is used, request to review the facility policy on these substances. The policy must include monitoring employee exposure, notification to employees exceeding allowable exposure levels and steps to take to lower employee exposure levels. • If EtO is used, observe the use of personal monitoring devices. • Review personnel files for evidence of staff training on the safe use, storage and handling of EtO and glutaraldehyde. Cite deficiencies in training at 11-I-11. • Review facility policy related to use of glutaraldehyde. • Review monitoring documentation to confirm employee exposure is being monitored and results are within limits set by NIOSH. **OSHA_ethylene_oxide.pdf** **glutaraldehyde.pdf (osha.gov)**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-G-2	Personnel are properly trained in the control procedures and work practices that have been demonstrated to reduce occupational exposures to anesthetic gases.	C	**Interpretive Guidance:** The intent of this standard is to ensure that staff have been properly trained in general workplace controls to minimize occupational exposures to anesthetic gases upon hire and annually thereafter. These controls include Engineering Controls, Work Practices, Administrative Controls, and Personal Protective Equipment. **Evaluating Compliance:** • Review the training materials to validate all training areas are covered: Engineering Controls, Work Practices, Administrative Controls, and Personal Protective Equipment. • Interview staff. • Review personnel files to ensure that staff have been trained in the control procedures and work practices to reduce occupational exposures to anesthetic gases. **Anesthetic Gases: Guidelines for Workplace Exposures | Occupational Safety and Health Administration (osha.gov)** **World Health Organization Exposure to Hazardous Chemicala** https://www.who.int/tools/occupational-hazards-in-health-sector/exposure-to-hazardous-chemicals **National Library of Medicine Principles of Environmental-Sustainable anaesthesia: A Global Consensus Statement from the World**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Federation of Societies of Anaesthesiologists, 2022 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9298028/	
3-G-3	There is a written policy for what is considered to be personal protective equipment for specific tasks in the facility (eg, instrument cleaning, disposal of biological waste, surgery, radiology protection, exposure reduction, etc.).	A B C	**Interpretive Guidance:** The intent is to ensure that staff utilize appropriate personal protective equipment for specific tasks. **Evaluating Compliance:** • Review policies and procedures and confirm there is a policy for what personal protective equipment is required for specific tasks in the facility.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION H: X-Ray and Laser Safety				
3-H-1	Laboratory and Radiologic Services.	416.49 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-H-2	If laboratory services are provided, these laboratory services must be provided in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR 493 operating under a current CLIA certificate appropriate to the level of services performed.	416.49(a) Standard A B C	**Interpretive Guidance:** The intent is to ensure that laboratory services are performed safely and accurately. **Evaluating Compliance:** • Review the facility's CLIA certificate and ensure the type of certificate is consistent with the lab services provided (i.e., waived, microscopy, moderate complexity) and that the Lab Director is correct. • Interview staff regarding running controls and any necessary calibration of lab equipment (all as recommended in the IFU). • Review records of quality control testing and patient lab services. **eCFR Part 493-Laboratory Requirements** https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493 **CMS How to Apply for a CLIA Certificate, Including International Laboratories** https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/apply **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-H-3	If x-ray equipment is used, safety measures are taken to protect patients and staff from injury. Warnings and signage exist to warn those whose health may be affected by x-rays.	A B C	**Interpretive Guidance:** This intent is to maintain patient and staff safety from exposure to radiation. Staff must wear the proper protective gear, such as lead aprons, thyroid shields, and goggles. Mobile shields and lead curtains should be used, when possible, to protect patients. X-ray imaging, which uses ionizing radiation, can potentially damage DNA. Ensuring that individuals are made aware that this equipment is in use can signal the need for protective equipment or the need to leave the immediately affected area. **Evaluating Compliance:** • Observe staff use of protective gear when using X-ray equipment. • Observe how lead aprons are stored. They should not be hanging over chairs, etc. Creases break down the lead's protection. • Confirm that the facility is following the manufacturer's instructions regarding x-ray safety. • Review facility policies and procedures and confirm policy in place with instructions on utilization of x-rays during pregnancy. • Review personnel files and confirm staff were notified related to occupational exposure to radiation. • Observe signage and warnings posted near the area where X-ray equipment is being used.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Medical X-ray Imaging | FDA **https://www.fda.gov/radiation-emitting-products/medical-imaging/medical-x-ray-imaging#risks** **The Radiology Information Resource for Patients** https://www.radiologyinfo.org/en **Radiation Dose** http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray **Health Physics Society Public Information Committee** **http://hps.org/publicinformation/** **Journal of the American Dental Association Optimizing Radiation Safety in Dentistry, 2024** https://jada.ada.org/article/S0002-8177(23)00734-1/fulltext?_gl=1*1t7n6dl*_gcl_au*MzQ1MDk4MjI3LjE3MTc3MjUwMzU.*_ga*NjQ5NzI1NDczLjE3MTc3MjUwMzU.*_ga_X8X57NRJ4D*MTcxNzgwOTE5Mi43LjEuMTcxNzgwOTQwNi4wLjAuMA..#secsectitle0145)	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-H-4	If X-ray is used, staff maintain dosimetry badges and records, if applicable, for at least three (3) years.	A B C	**Interpretive Guidance:** The intent is to ensure facilities use individual badges - not area dosimetry. Badges should be worn every day in the neck or chest area facing the radiation source. If you wear a lead apron the badge must be worn OVER the lead. Do not borrow or loan badges to others. **Evaluating Compliance:** • Review the facility policy on dosimetry badges for compliance. • Observe the staff for the proper use of dosimetry badges while operating the X-ray equipment. • Review facility documentation that radiation exposure was measured with dosimetry badges and results reviewed with employees quarterly or more frequently, as required by state and/or federal law	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
3-H-5	Radiologic services may only be provided when integral to procedures offered by the facility and must meet the requirements specified in 42 CFR 482.26(b), (c)(2), and (d)(2).	416.49(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
3-H-6	If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and facility policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of 42 CFR 416.49.	416.49(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
3-H-8	If a laser is used, all manufacturer recommended safety precautions are actively in place prior to any usage. All safety measures are taken to protect patients and staff from injury, including appropriate eyewear, covered mirrors, covered windows, signage on the door, etc. in accordance with state/provincial laws and regulations.	A B C	**Interpretive Guidance:** The intent is to ensure that safety measures are instituted to protect patients and staff from injury. If a laser is used during procedures, the manufacturer's user manual is present and available for use. A policy and procedure is in place and staff training occurs on hire and annually thereafter. **Evaluating Compliance:** • Are procedures performed in the facility consistent with the current version of the ANSI Standard for Safe Use of Lasers in Health Care Facilities? • Are all procedures performed according to the manufacturer's instructions for use • Are safe practices in place when using laser equipment. • Staff working with laser devices are trained prior to participating in procedures using these devices.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

SECTION 4: EQUIPMENT

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Facility Equipment				
4-A-1	If a central source of piped oxygen is used, the system must meet all applicable local, state/provincial, country safety codes	A B C	**Interpretive Guidance:** The intent is to ensure that the oxygen level prescribed is actually delivered to the patient. The manufacturer's instructions shall include directions and information deemed adequate for the proper operation, testing, and maintenance of the medical gas and vacuum systems. Centrally plumbed oxygen compliance should be verified by an American Society of Safety Engineers (ASSE) 6030 (independent gas verifier's certificate) for compliance to the appropriate Category level. Inspection and testing reports are maintained by the facility. **Evaluating Compliance:** • Request and review the most recent inspection and testing reports. • Are the inspections and testing done in accordance with the manufacturer's instructions for the proper testing and maintenance? • If issues were identified, was remedial action taken to correct the problem	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Was the testing and maintenance conducted by a qualified independent gas verifier? Preferably one certified by the ASSE 6030, **The National Fire Protection Agency (NFPA) 99, 2012** https://up.codes/viewer/centers-for-medicare-and-medicaid-services/nfpa-99-2012/chapter/5/gas-and-vacuum-systems#5 **World Class Healthcare Compliance, Medical Gas Systems: The Definitive Guideline** https://f.hubspotusercontent20.net/hubfs/479873/bonus%20content/medical-gas-systems-guide.pdf?__hstc=1717358.4f83df3156ea0e81eee9d942814fad43.1726598873503.1726598873503.1726598873503.1&__hssc=1717358.1.1726598873503&__hsfp=2901579814&hsCtaTracking=4a8af79e-62cb-4897-ae24-627d87fe0fcc%7C030bdec8-b6d4-44c4-b056-b9088173751a	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-A-2	Medical equipment and supplies are available in the facility in appropriate sizes and quantities based on the patient population served**.**	A B C	**Interpretive Guidance:** The intent is to ensure that the appropriate medical equipment and supplies are available in the facility based on the patient population served. This includes both adults and pediatric populations, as appropriate. If the facility serves pediatric patients, the facility defines its pediatric population. **Evaluating Compliance:** • Observe the medical equipment and supplies available in the facility. Are they sufficient for the patient population served, both adult and pediatric? • Interview staff.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Operating Room Equipment				
4-B-2	There is a properly functioning and operating room table or chair.	A B C	**Interpretive Guidance:** The intent is to ensure patient safety. **Evaluating Compliance:** • Observe the operating room table and/or chair to determine if they function properly. • Interview staff regarding functionality.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-B-3	The operating room is provided with sufficient and adequately functioning lighting in the ceiling based on the types of cases performed. Adequate illumination for patients, machines, and monitoring equipment, which must include battery-powered illuminating systems, are present.	A B C	**Interpretive Guidance:** The intent is to ensure proper lighting for surgical cases. **Evaluating Compliance:** • Observe all operating room lighting. Is it adequate for the types of cases performed? • Interview staff regarding the adequacy of ceiling lighting and illumination for patients, machines, and monitoring equipment. • Are battery-powered illuminating systems present?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
4-B-5	Sufficient electrical outlets are available, labeled and grounded to suit the location (e.g.; wet locations) and connected to emergency power supplies where appropriate.	A B C	**Interpretive Guidance:** The intent is to ensure the electrical outlets are appropriate to the types of surgical cases and procedures performed. Operating rooms are considered wet procedure locations unless a risk assessment conducted by the owner or the owner's life safety consultant deems otherwise. Due to the invasive nature of the procedures, wet procedure locations require special protection against electrical shock. **Evaluating Compliance:** • Observe the electrical outlets. Are they sufficient to accommodate all equipment used? • Are outlets labeled and grounded based on the location?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Are the outlets connected to emergency power supplies, when appropriate? • Interview staff regarding the adequacy of electrical outlets.	
4-B-6	Sequential compression devices (SCD) are employed for operations lasting one (1) hour or longer, except for operations carried out solely under local or topical anesthesia.	B C	**Interpretive Guidance:** The intent is to minimize the risk of venous thromboembolism (VTE) and deep vein thrombosis (DVT) in those patients who will be in the OR or procedure room > than 60 minutes. The SCDs should be in place prior to the procedure and remain in place until the patient is ambulatory unless contraindicated. The facility should have a policy in place that describes when and how to use the selected SCDs. SCDs may not be indicated for use with pediatric patients (less than 13 years old). **Evaluating Compliance:** • Review facility policy • Is a risk assessment conducted? SCDs may not be indicated based on the level of sedation and type of procedure. For example, if the procedure involves a lower limb, or if the patient is small	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review clinical record documentation for documented evidence that SCDs were utilized during procedures lasting one (1) hour or longer. • Observe practice. • Interview staff regarding the use of SCDs **American Nurse, Enhancing patient outcomes with sequential compression device therapy, 2013** https://www.myamericannurse.com/enhancing-patient-outcomes-with-sequential-compression-device-therapy/	
4-B-7	A source of cautery is present in the operating room. When unipolar electrocautery is used, a single-use/ disposable or reusable grounding pad is used.	B C	**Interpretive Guidance:** The intent is to safeguard patients and staff from electrocution. Electrosurgical cautery devices are commonly used in various medical procedures to achieve hemostasis, cut tissues, and coagulate blood vessels. These devices utilize electrical energy to generate heat and perform precise surgical procedures. High-temperature cautery pens (heat pens) do not require collector pads. Unipolar electrocautery equipment must be used and maintained according to the manufacturer's instructions for use (IFUs). **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Observe the presence of cautery in the OR. • Review the manufacturer's information for use and the facility's documentation that the cautery has been tested at least annually. • Observe the type of unipolar electrocautery used. Are they used in accordance with the manufacturer's IFUs? • If reusable, are the grounding pads reprocessed and maintained in accordance with the manufacturer's IFUs? • Observe practice when possible. • Interview staff regarding the types of unipolar electrocautery devices used. Are they single-use/ disposable or reusable? If reusable, how are they maintained? Are they reprocessed in accordance with the manufacturer's IFUs? **AORN eGuidelines, Electrosurgical Safety, 2020** https://aornguidelines.org/guidelines/content?sectionid=173718992&view=book#229131846	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-B-8	"Forced air warmers," blanket warmers, or other devices are used to maintain the patient's temperature. The patient's temperature is monitored periodically to ensure normothermia.	C	**Interpretive Guidance:** The intent is to ensure that the patient's temperature is maintained during all anesthetics. This standard applies when significant changes in patient temperature are anticipated. The facility defines in policy the meaning of "significant changes" in temperature. The temperature in the operating room environment, combined with the use of general anesthesia agents, places surgical patients at an increased risk for the development of perioperative hypothermia. Patient warming prevents inadvertent perioperative hypothermia, which can cause vasoconstriction, tissue hypoxia, and a decreased ability to fight infections. Perioperative warming also increases patient satisfaction and helps to reduce lengths of stay in the PACU. To ensure patients are properly warmed, a patient warming checklist should be included in the facility's policies and procedures. Essential elements include: • If the patient is not pre-warmed, start active warming prior to induction of anesthesia. • Warm intravenous fluids and blood products to 37°C.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Warm irrigation fluids used intraoperatively in a thermostatically controlled cabinet to 38°C to 40°C. • Document temperature routinely (every five minutes, for example). • Measure core temperatures whenever possible. • Induction of anesthesia should not begin unless the patient's temperature is 36°C or above. • Actively warm patients intraoperatively if they'll be anesthetized for more than 30 minutes or if they'll be sedated for less than 30 minutes and are at higher risk of inadvertent perioperative hypothermia. • The temperature setting on warming devices should be set to maintain a patient temperature of at least 36.5°C. • Measure and document patients' temperatures upon admission to PACU and then every 15 minutes thereafter until a normothermic reading is achieved. • Discharge should not be arranged unless the patient's temperature is 36°C or above. If it is below 36°C, the patient should be actively warmed until normothermia is reached. • The temperature of warming devices must be monitored, and the facility must have a policy and procedure for	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			actions to take when the temperature of the warming device is out of range. **Evaluating Compliance:** • Review facility policies and procedures regarding patient warming. • Interview staff. • Review clinical records. • Review temperature monitoring logs. • Observe practice if possible **Association of Anaesthetists Peri-operative waming devices: performance and clinical application, 2014** https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1111/anae.12626 **Article | Outpatient Surgery Magazine (aorn.org) Patient Warming's Preventative Benefits, 2021** https://www.aorn.org/outpatient-surgery/article/2021-May-patient-warming-benefits **Safety and efficacy of resistive polymer versus forced air warming in total joint surgery | Patient Safety in Surgery | Full Text (biomedcentral.com)** https://pssjournal.biomedcentral.com/articles/10.1186/s13037-017-0126-0 **AORN Outpatient Surgery, Implementing Safe and Effective Patient Warming, 2022**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.aorn.org/outpatient-surgery/article/2022-June-patient-warming	
SUB-SECTION C: Anesthesia Equipment				
4-C-1	The operating room is equipped with an EKG monitor with pulse read-out.	B C	**Interpretive Guidance:** The intent is to ensure the adequacy of the patient's circulatory function during all anesthetics. **Evaluating Compliance:** • Observe the presence of an EKG monitor in the OR. • Review the manufacturer's information for use and the facility's documentation that the equipment has been tested at least annually. • Interview staff regarding use. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	
4-C-2	The operating room is equipped with a pulse oximeter.	B C	**Interpretive Guidance:** The intent is to ensure patient safety through pulse oximeter monitoring. **Evaluating Compliance:** • Observe the presence of a pulse oximeter in the OR. • Review the manufacturer's information for use and the facility's documentation that the equipment has been tested at least annually. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-3	The operating room is equipped with blood pressure monitoring equipment, including cuff sizes as appropriate for the patient population treated in the facility.	A B C	**Interpretive Guidance:** The intent is to ensure the adequacy of the patient's circulatory function during all anesthetics. **Evaluating Compliance:** Observe the presence of blood pressure monitoring equipment in the OR. Is the cuff size appropriate for the population served? **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
4-C-4	The operating room is equipped with oral airways including sizes specific for each size of patient population treated in the facility.	B C	**Interpretive Guidance:** The intent is to ensure patient safety when an oral airway is needed. **Evaluating Compliance:** Observe the presence of oral airways for each size for the patient population treated in the facility. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Standards for Basic Anesthetic Monitoring (asahq.org), 2020 https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	
4-C-5	The operating room is equipped with nasopharyngeal airways including sizes for each size of patient population treated in the facility.	B C	**Interpretive Guidance:** The intent is to ensure patient safety when a nasopharyngeal airway is required. **Evaluating Compliance:** Observe the presence of oral airways in each size needed for the patient population treated in the facility. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-6	The operating room is equipped with a functional and clean laryngoscope. Laryngoscope is cleaned as appropriate, HLD or sterilized. Permitted in Class B for emergency use only.	B C	**Interpretive Guidance:** The intent is to ensure patient safety when a laryngoscope is required. Laryngoscope handles and blades must be disinfected or sterilized according to the manufacturer's IFU and then stored in a manner that identifies the device as clean and prevents cross-contamination. Examples of compliant storage include a peel pack post steam sterilization (long-term) or wrapping in a sterile towel (short-term). Examples of non-compliant storage would include unwrapped blades in an anesthesia drawer or on top of an emergency cart. Laryngoscope batteries and laryngoscope blade light bulbs are checked at least monthly. **Evaluating Compliance:** • Observe the storage of laryngoscope blades to ensure packaging is sealed to prevent recontamination. • Test a sample of blades to ensure they are functional. • Review facility policy related to the cleaning and testing of equipment. • Interview staff regarding cleaning and testing equipment. • Review documentation of cleaning. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	
4-C-7	The operating room is equipped with a comprehensive assortment of endotracheal tubes, stylets, and laryngeal mask airways including sizes and types for the patients being treated in the facility. Permitted in Class B for emergency use only.	B C	**Interpretive Guidance:** The intent is to ensure patient safety when an endotracheal tube and stylet, or laryngeal mask airway is required. **Evaluating Compliance:** Observe the endotracheal tubes, stylets, and laryngeal airways available to ensure a comprehensive assortment for the patients being treated. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-9	The operating room is equipped with a positive pressure ventilation device (e.g. Ambu® bag, bag valve mask), including sizes of masks to cover the range needed for the patient population treated in the facility. If self-inflating bags are used, they must be capable of delivering positive-pressure ventilation with at least 90% oxygenation concentration.	A B C	**Evaluating Compliance:** • Observe the presence of positive pressure ventilation device(s) in the OR. • If self-inflating bags are used, are they capable of delivering positive-pressure ventilation with at least 90% oxygen concentration? • Inspect the integrity of the positive pressure ventilation device along with its expiration date. **Consensus Recommendations for the Safe Conduct of Nonoperating Room Anesthesia: A Meeting Report From the 2022 Stoelting Conference of the Anesthesia Patient Safety Foundation - Anesthesia Patient Safety Foundation (apsf.org)** https://pubmed.ncbi.nlm.nih.gov/32809751/ **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-10	The operating room is equipped with a source of oxygen and with appropriate delivery devices (e.g. nasal cannula, face mask) to provide adequate oxygen for the patient population treated and procedures performed in the facility.	A B C	**Interpretive Guidance:** The intent of this standard is to ensure patient safety when oxygen is required. **Evaluating Compliance:** Observe that the OR is equipped with oxygen. Are appropriate delivery devices present and ready for use? **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **Understanding noninvasive ventilation, 2021** https://www.myamericannurse.com/understanding-noninvasive-ventilation/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-11	The operating room is equipped with a source of adequate and reliable suction and suction equipment.	A B C	**Interpretive Guidance:** The intent is to ensure patient safety when suction is required. **Evaluating Compliance:** • Observe the presence of suction equipment in the OR. Is it adequate and reliable? • Turn the suction on to verify its functionality. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
4-C-12	The operating room is equipped with a reliable source of oxygen, adequate for the length of the procedures performed in the facility (back up must consist of at least one full E cylinder). Back up oxygen source must have a regulator on it and be ready to use. If oxygen cylinders are used as backup, they must be full.	A B C	**Interpretive Guidance:** The intent is to ensure patient safety when oxygen is required. **Evaluating Compliance:** • Observe the operating room's oxygen source. Is it adequate for the length of procedures performed in the facility? • Is a backup oxygen source present with a regulator? Is it ready for use?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Are oxygen cylinders used for backup? If yes, are they full? **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **Understanding noninvasive ventilation, 2021** https://www.myamericannurse.com/understanding-noninvasive-ventilation/ **Indian Journal of Aneaesthesia, Anaaesthesia Gas Supply: Gas Cylinders, 2013** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3821267/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-13	If inhalation general anesthesia is used, the operating room is equipped with an inspired gas oxygen monitor on the anesthesia machine with an audible alarm to indicate a low oxygen concentration.	C	**Interpretive Guidance:** The intent is to ensure safe patient oxygen concentration during inhalation of general anesthesia. This device will detect if O2 is not flowing through the anesthesia machine and the mixture of gases. **Evaluating Compliance:** • Observe the anesthesia machine for evidence of an inspired gas oxygen monitor. Is it equipped with an audible alarm to indicate low oxygenation? • Interview staff regarding the use of the anesthesia machine and oxygen monitor. **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **International Standardards Organization (ISO) ISO5358"1992(en) Anaesthetic machines for use with humans, 1992**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.iso.org/obp/ui/#iso:std:iso:5358:ed-2:v1:en **ISO5358"1992(en) Continuous flow inhalational anaesthetic apparatus (anaesthetic machine) for use with humans, 1992** https://cdn.standards.iteh.ai/samples/11384/8da97623dbe74f6ab594cc26391c7c76/ISO-5358-1980.pdf	
4-C-14	The operating room is equipped with an end-tidal carbon dioxide monitor with an audible alarm on to indicate values outside the normal range which is used on all moderate sedation, deep sedation, and general anesthesia cases.	B C	**Interpretive Guidance:** The intent is to ensure adequate ventilation of the patient receiving moderate and deep sedation and general anesthesia cases. End-tidal carbon dioxide ($ETCO_2$) monitoring provides valuable information about CO_2 production and clearance (ventilation). Also called capnometry or capnography, this noninvasive technique provides a breath-by-breath analysis and a continuous recording of ventilatory status. It is commonly called the "ventilation vital sign." 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.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Observe the operating room. Is there an end-tidal carbon dioxide monitor? Does it have an audible alarm to indicate values outside the range? • Interview staff. Is it used in all moderate and deep sedation, and general anesthesia cases? • Review clinical records to validate end-tidal monitoring on all moderate and deep sedation, and general anesthesia cases? **AANA Documenting Anesthesia Care, 2016** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **American Nurse, Understanding end-tidal CO2 monitoring, 2012** https://www.myamericannurse.com/understanding-end-tidal-co2-monitoring/ **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.asahq.org/standards-and-practice-parameters/statement-on-continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia	
4-C-15	When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting the disconnection of any of the breathing system's components. The device must give an audible signal when its alarm threshold is exceeded.	C	**Interpretive Guidance:** The intent is to ensure patient safety when mechanical ventilation is used. **Evaluating Compliance:** • Observe the mechanical ventilator(s) used. • Is a device used capable of detecting the disconnection of any of the breathing components? • Does the device provide an audible alarm when its threshold is exceeded? **Standards for Basic Anesthetic Monitoring (asahq.org), 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **International Standards Organization (ISO) ISO5358"1992(en) Anaesthetic machines for use with humans, 1992**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.iso.org/obp/ui/#iso:std:iso:5358:ed-2:v1:en **ISO5358"1992(en) Continuous flow inhalational anaesthetic apparatus (anaesthetic machine) for use with humans, 1992** https://cdn.standards.iteh.ai/samples/11384/8da97623dbe74f6ab594cc26391c7c76/ISO-5358-1980.pdf	
4-C-16	If nitrous oxide alone is used, then a safe delivery system is used. A safe delivery system meets these criteria: 1) Alarms 2) Gas scavenging 3) Color coding of tanks, knobs, and hoses 4) Diameter index safety system for non-interchangeable connection of gases - pin index safety system 5) Oxygen fail-safe system and oxygen flush capacity 6) Quick connection for positive-pressure oxygen delivery 7) Emergency air inlet 8) Reservoir bag 9) Storage in secured area	A B C	**Interpretive Guidance:** The intent is to ensure the safe delivery of nitrous oxide. See standard 3-A-1 and the Nitrous Oxide Addendum and references contained in the Anesthesia Class document. **Evaluating Compliance:** Observe the oxygen delivery system. Does it contain the necessary safeguards? See standard 3-A-1 and the Nitrous Oxide Addendum and references contained in the Anesthesia Class document. **National Library of Medicine, Pin Index Safety, 2022** https://www.ncbi.nlm.nih.gov/books/NBK532908/#article-27225.s1 **Anaesthesia Gas Supply: Gas Cylinders - PMC, 2013**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3821267/	
4-C-17	An anesthesia machine with a purge system to extract exhaled gaseous air to out-of-doors or to a neutralizing system is present. If inhalation anesthesia is used, a carbon–dioxide-neutralizing system is required when using an anesthesia machine. An adequate and reliable waste anesthetic scavenging system exists if inhalation anesthetics are used.	C	**Interpretive Guidance:** The intent is to ensure the safety of the patient and staff when an anesthesia machine is in use. The purge and waste scavenging systems aim to remove as much residual anesthetic gases as possible, reducing patient and staff exposure. **Evaluating Compliance:** • Observe the Anesthesia machine. Does it have a purge system? • If inhalation anesthesia is used, is a carbon-dioxide—neutralizing system present and used with an anesthesia machine? • Is an adequate and reliable waste anesthetic scavenging system used when inhalation anesthetics are used? • Interview staff. **OSHA Anesthetic Gases: Guidelines for Workplace Exposures, 2000** https://www.osha.gov/waste-anesthetic-gases/workplace-exposures-guidelines	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-C-18	An anesthesia machine is required if volatile agents are available in the facility. If total intravenous anesthesia (TIVA), spinal, or epidural anesthesia is used exclusively, and no volatile inhalation agents are available, an anesthesia machine is not required.	C	**Interpretive Guidance:** If an anesthesia machine is present and accessible to the facility, it is presumed that general anesthesia is being provided. In these cases, the facility is expected to comply with all Class C standards. **Evaluating Compliance:** Is an anesthesia machine available? Are volatile agents available in the facility?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION D: Post-Anesthesia Care Unit (PACU) Equipment				
4-D-1	The PACU is equipped and readily accessible to handle emergencies	B C	**Interpretive Guidance:** The intent is that the PACU has adequate equipment readily accessible for the safe provision of care and to respond to emergencies. An emergency cart must be immediately accessible for emergencies. If the facility treats pediatric patients, pediatric-sized resuscitation equipment is immediately accessible. **Evaluating Compliance:** • Observe that all required equipment and sizes, medications, and supplies are present for the patient population served. • Interview staff regarding the PACU procedure in the event of an emergency. • Verify the presence of pediatric equipment available, if the facility treats pediatrics	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-D-2	A separate pulse oximeter is available for each patient in the PACU.	B C	**Interpretive Guidance:** The intent is for the facility to have a pulse oximeter available for all patients to monitor blood oxygen levels. **Evaluating Compliance:** • Observe patient use of pulse oximeters. Is there a pulse oximeter for each patient in PACU? • Interview the staff regarding policy and procedures.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION E: Maintenance of Equipment				
4-E-1	The facility has a preventive maintenance program to ensure that all **essential** mechanical, electric and patient-care equipment is maintained in safe operating condition and is replaced no less frequently than according to a schedule. A qualified technician annually inspects all equipment and reports in writing that the equipment is safe and operating according to the manufacturer's specifications. Stickers may be placed on individual equipment; however, written records must be maintained. All equipment is on a maintenance schedule, and records are kept for a minimum of at least three (3) years.	A B C	**Interpretive Guidance:** The intent is that all essential equipment is maintained and safe for use in patient care. All equipment is inspected when initially brought into the facility, prior to use in patient care, and annually thereafter. The qualified technician may be a biomedical technician/engineer, electrical technician/engineer, medical technician/engineer, life safety code technician/engineer, or equipment manufacturer. The individual must be trained or certified to inspect and maintain specific equipment. **Evaluating Compliance:** • Review and validate the equipment maintenance plan.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Randomly select several pieces of equipment and review the facility's maintenance and inspection records. Are records available for the last three (3) years? Are inspections conducted by a qualified technician? • Observe equipment maintenance sticker inspection dates. • Interview staff to see if they can recognize whether the equipment has been tested or needs to be tested. • Interview staff to determine if they know when a piece of equipment is unsafe to use and the process for removing it from use.	
4-E-5	The manufacturer's specifications and requirements for all equipment are kept in an organized file and followed for each piece of equipment.	A B C	**Interpretive Guidance:** The intent is that the facility maintains the manufacturer's specifications and recommendations requirements for all equipment used in the facility. **Evaluating Compliance:** • Review the facility's file on the manufacturer's specifications and requirements for all equipment. Randomly select several pieces of equipment to validate inclusion in the file. • Interview staff. • Select a few random pieces of equipment and ask to see the manufacturer's specifications and recommendations requirements on file for the pieces of equipment.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
4-E-7	Central/Plumbed/Piped Anesthesia gas systems, including nitrous delivery system, are checked by a qualified inspector and written reports are available stating that the equipment is safe and operating according to the manufacturer's specifications.	A B C	**Interpretive Guidance:** The intent is that the facility has an inspection process in place to ensure patient safety when central/plumbed/piped anesthesia gas systems are used, including the nitrous delivery system, that is checked by a qualified inspector. Centrally plumbed oxygen compliance should be verified by an American Society of Safety Engineers (ASSE) 6030 (independent gas verifier's certificate) for compliance to the appropriate Category level. Inspectors are certified when required by state law. Inspection and testing reports are maintained by the facility. **Evaluating Compliance:** • Review the facility's policies and procedures • Review written reports to ensure inspection compliance. **NFPA 99, 2012 Chapter 5 Gas and Vacuum Systems** https://up.codes/viewer/centers-for-medicare-and-medicaid-services/nfpa-99-2012/chapter/5/gas-and-vacuum-systems#5 **World Class Healthcare Compliance, Medical Gas Systems: The Definitive Guideline**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://f.hubspotusercontent20.net/hubfs/479873/bonus%20content/medical-gas-systems-guide.pdf?__hstc=1717358.4f83df3156ea0e81eee9d942814fad43.1726598873503.1726598873503.1726598873503.1&__hssc=1717358.1.1726598873503&__hsfp=2901579814&hsCtaTracking=4a8af79e-62cb-4897-ae24-627d87fe0fcc%7C030bdec8-b6d4-44c4-b056-b9088173751a	
4-E-8	Nitrous oxide/oxygen delivery safety system checks: Annual documented checks of ambient nitrous oxide levels should be less than 25 ppm according to NIOSH. The facility's policies and procedures document these system checks and address who is qualified to perform them, their frequency, the method of testing, and the action to e taken if the nitrous oxide levels are greater than 25 ppm in accordance with the manufacturer's instructions for use.	A B C	**Interpretive Guidance:** The intent is that the facility maintains, documents, and monitors annual checks of ambient nitrous oxide levels, which should be less than 25 ppm, in accordance with NIOSH, to ensure patient safety. **Evaluating Compliance:** • Review facility policies and procedures. • Interview staff. • Review nitrous oxide level reports to verify that the ambient nitrous oxide levels are less than 25 ppm. • Verify that appropriate action is taken when levels are less than 25 ppm. • Review the documentation for safety checks. **Controlling Exposures to Nitrous Oxide During Anesthetic Administration | NIOSH | CDC**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			NIOSH Controlling Exposures to Nitrous Oxide During Anesthetic Administration, 1994 https://www.cdc.gov/niosh/docs/94-100/pdfs/94-100.pdf?id=10.26616/NIOSHPUB94100	

SECTION 5: IN CASE OF EMERGENCY

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Emergency Equipment				
5-A-1	Emergency cart is immediately available with a defibrillator or automated external defibrillator (AED), necessary drugs, and other CPR equipment (e.g. suction, pediatric defib pads) necessary for the patient population being served.	A B C	**Interpretive Guidance:** The intent is to have all necessary equipment together in one place and immediately available to manage an emergency in the OR or PACU at all times a patient is in the facility. This also means that if a contract anesthesia provider brings any emergency medications or equipment into the facility and removes any of these items when leaving the facility, the contract anesthesia provider must remain in the facility until all patients have been discharged from the PACU. **Evaluating Compliance:** • Inspect the emergency cart to ensure that it is equipped with the required working equipment, medications, and other CPR equipment. • Interview staff regarding the emergency cart contents,	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-A-3	The standard defibrillator, or an Automated External Defibrillator (AED), is checked at least weekly for operability in accordance with the manufacturer's instructions for use, and the test results are documented and kept for a minimum of three (3) years.	A B C	**Interpretive Guidance:** This is to ensure that the standard defibrillator or AED functions properly in an emergency situation. Documentation of the checks is generally kept in a log that tracks who and when the defibrillator is checked, when the battery has been changed, etc., to ensure it is working and ready for emergency situations. Checks are done according to the manufacturer's instructions for use. The battery is tested with the defibrillator unplugged. Most AEDs have a battery life of two (2) to four (4) years. Depending on the brand, AED pads typically expire in two (2) years. **Evaluating Compliance:** • Review the manufacturer's instructions for use. • Interview staff regarding how the defibrillator or AED is checked. Is it consistent with the manufacturer's instructions for use? • Inspect the log to ensure that at least weekly tests have been conducted over the past three (3) years. • Interview staff regarding the replacement of batteries. • Inspect supplies, such as defibrillator pads, to ensure they have not expired.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			A Study on Performance and Safety Tests of Defibrillator Equipment - PMC (nih.gov) **Automated External Defibrillators (AEDs) | FDA FDA-Approved AED Devices**	
5-A-4	The facility medical staff, anesthesia professionals, other clinical staff, and the governing body of the facility coordinates, develops, and revises facility policies and procedures to specify the types of emergency equipment required for use in the facility's operating room.	416.44(d) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-A-5	The emergency equipment must be immediately available for the use of emergency situations.	416.44(d)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-A-6	The emergency equipment must be appropriate for the facility's patient population.	416.44(d)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-A-7	The emergency equipment must be maintained by appropriate personnel.	416.44(d)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Emergency Power				
5-B-2	The operating room(s) and PACU have an emergency power source, (e.g. a generator or battery powered inverter), with capacity to operate critical equipment (e.g., ventilators, lighting, monitoring, anesthesia, and procedure equipment) for a minimum of 90 minutes. If two or more operating rooms are used simultaneously, an adequate emergency power source must be available for all operating rooms.	B C	**Interpretive Guidance:** The intent is ensure all operating and recovery rooms (not individual pieces of equipment) are equipped with an emergency power source in the event of a power outage. The emergency power supply (EPS) is the source of electrical power (i.e., a generator) used in the backup power system (NFPA 7.9.1). It is independent of the primary source of power and is ready to kick on in case of power failure.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			A battery backup in a piece of equipment does not meet the requirement for an emergency power supply. Many pieces of medical equipment have a battery backup capable of lasting through most short-term power outages only. However, if there is a natural disaster and help is not immediately available, an emergency power source must be available. Egress lighting in hallways must be provided for a minimum of ninety (90) minutes in the event of normal lighting failure. The emergency lighting system shall either be continuously in operation or capable of repeated automatic operation without manual intervention. Emergency lighting for at least 90 minutes is required. Photoluminescent exit signs are permissible. The facility must have a policy related to the emergency power source, which must include the frequency of testing, steps to take if the system fails to sustain critical equipment for the required timeframe, and record retention. **Evaluating Compliance:** • Review facility policy related to its emergency power system. • Review facility documentation to ensure testing has occurred within the required timeframes and that the system has passed the tests. • Interview staff on steps taken if any failures are noted in the log.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			The No-Nonsense Guide to NFPA 110 Compliance for Emergency Power Systems https://ckpower.com/wp-content/uploads/2018/04/NFPA-110-Final.pdf **CMS S&C 07-21 Generators in Ambulatory Surgical Centers (ASC)** www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter07-21.pdf	
SUB-SECTION C: Emergency Protocols				
5-C-1	There must be a written protocol for emergency evacuation of the facility. The protocol must include provisions for annual drills for the emergency evacuation of patients, staff, and guests, staff training upon hire and annually. Documentation of all drills must be retained in the facility for a minimum of three (3) years.	A B C	**Interpretive Guidance:** The best way to protect staff and patients is to expect the unexpected and to carefully develop an emergency action plan to guide everyone in the workplace when immediate action is necessary with a clear set of roles and responsibilities. Planning in advance helps ensure that everyone knows what to do when an emergency occurs. For annual drills, it is recommended that the facility conduct one (1) drill per quarter: emergency evacuation, fire safety, security, and CPR emergencies. The protocol is reviewed and tested annually and updated as necessary. All staff are expected to have received training on this protocol: upon hire, annually, and as any updates or revisions to the protocol are made. **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the facility protocol for emergency evacuation of the facility. Is the protocol reviewed annually? • Interview staff to assess knowledge of this protocol. • Review drill documentation. Are records retained for at least three (3) years? • Are drills conducted at least annually? • Review staff records to determine that the appropriate training has been provided initially upon hire and annually thereafter, and any time updates occur. Cite deficiencies in training at 11-I-4.	
5-C-2	A written protocol for security emergencies, such as an intruder in the facility, an unruly patient or visitor, or a threat to the staff or patients, must be documented and reviewed annually. The protocol must include provisions for annual drills for security emergencies; staff traning upon hire and annually; drill documentation; and, retention of documentation for a minimum of three (3) years.	A B C	**Interpretive Guidance:** There is a written protocol that outlines required activities in the event there is a security emergency. Security emergencies would include: • Intruders • Unruly patient or visitor • Bomb threat • Other threats to staff or patients Drills should reflect different locations and scenarios. An after-action report is completed. The protocol is reviewed and tested annually and updated as necessary. As with any policy and procedure, staff are expected to be trained on this protocol upon hire and annually. The protocol itself should be reviewed and updated (as necessary) annually.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Review the facility protocol for security emergencies and that the protocol has been reviewed annually. • Interview staff regarding what they would do in various scenarios. • Review drill documentation. Are records retained for at least three (3) years? • Review personnel files to determine the appropriate training has been provided initially upon hire and annually thereafter, and any time updates occur. Cite deficiencies in training at 11-I-4.	
5-C-3	There must be a written protocol for fires and fire drills. This protocol must include the provision for: fire drills; staff training upon hire and annually; drill documentation and retention of documentation for a minimum of three (3) years.	A B C	**Interpretive Guidance:** Knowing what to do in a fire is critical to protecting the health and safety of patients, visitors, and staff. A comprehensive protocol describing what to do during a fire is the first step in ensuring this protection. Drills should reflect different locations and scenarios. The protocol is reviewed and tested annually and updated as necessary. **Evaluating Compliance:** • Interview staff regarding what they would do in case of a fire and assess their knowledge of the facility's fire protection protocol. Ask staff how often fire drills are conducted.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the facility's fire protocol for all required elements. • Review documentation that fire drills have occurred at least quarterly. **AORN Sample Fire Safety Policy** **Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication | FDA (archive-it.org)**	
5-C-4	There must be a written protocol for returning patients to the operating room or transfer to the hospital in the event of patient emergencies.	A B C	**Interpretive Guidance:** The intent is that the facility has a protocol in place to provide guidance to ensure the patient remains safe should a return to the OR be required. This protocol should, at a minimum, include who to contact (family, anesthesia, the charge RN, outside emergency assistance, etc.), keeping the patient NPO, how records will be kept, how consent will be obtained, and when to report the event to QUAD A via the Patient Safety Data Reporting system. The protocol is reviewed annually and updated as necessary The protocol is reviewed annually and updated as necessary. **Evaluating Compliance:** • Interview staff to assess knowledge of the return to OR protocol.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the protocol for all required elements and evidence that the protocol is reviewed and revised annually.	
5-C-7	There must be a written protocol for a situation in which the surgeon/proceduralist, anesthesia professional, or other healthcare professional is impaired or becomes incapacitated.	A B C	**Interpretive Guidance:** Staff should be knowledgeable about how to handle situations where the surgeon, anesthesiologist, CRNA, or other healthcare professional is impaired or incapacitated. The facility protocol should be easily accessible to staff and outline appropriate steps to take in these situations. The protocol is reviewed annually and updated as necessary. **Evaluating Compliance:** • Interview staff regarding their knowledge of what to do should a healthcare professional be found to be impaired or incapacitated. • Review facility protocol to ensure appropriateness. • Review personnel files to ensure that staff training has occurred upon hire and annually thereafter. Cite deficiencies in training at 11-I-4. •	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: Emergency Preparedness Plan				
5-D-1	The Provider/Supplier must comply with all applicable Federal, State, and local emergency preparedness requirements. The Provider/Supplier must establish and maintain an emergency preparedness program that meets the requirements of this section.	416.54 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-2	Emergency plan: The Provider/Supplier must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every two (2) years.	416.54(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-3	The plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.	416.54(a)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-4	The plan must include strategies for addressing emergency events identified by the risk assessment.	416.54(a)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-5	The plan must address patient population, including, but not limited to, the type of services the Provider/Supplier has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.	416.54(a)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-6	The plan must address the location and use of alarm systems and signals; and methods of containing fire.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-7	The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.	416.54(a)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-9	Policies and procedures: The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, and the communication plan in standard 5-D-21. The policies and procedures must be reviewed and updated at least every two (2) years.	416.54(b) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-10	At a minimum, the policies and procedures must address a system to track the location of on-duty staff and sheltered patients in the Provider/Supplier care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the ASC must document the specific name and location of the receiving facility or other location.	416.54(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-11	At a minimum, the policies and procedures must address safe evacuation from the Provider/Supplier..	416.54(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-12	Safe evacuation from the Provider/Supplier must include consideration of care and treatment needs of evacuees.	416.54(b)(2) Standard 416.54(b)(2) (i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-13	Safe evacuation from the Provider/Supplier must include staff responsibilities.	416.54(b)(2) Standard 416.54(b)(2) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-14	Safe evacuation from the Provider/Supplier must include transportation.	416.54(b)(2) (iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-15	Safe evacuation from the Provider/Supplier must include identification of evacuation locations, such as appropriate placement of exit signs.	416.54(b)(2) (iv) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-16	Safe evacuation from the Provider/Supplier must include primary and alternate means of communication with external sources of assistance.	416.54(b)(2) (v) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-17	At a minimum, the policies and procedures must address a means to shelter in place for patients, staff, and volunteers who remain in the Provider/Supplier.	416.54(b)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-18	At a minimum, the policies and procedures must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.	416.54(b)(4) (i) Standard 416.54(b)(4) (ii) Standard 416.54(b)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-19	At a minimum, the policies and procedures must address the use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.	416.54(b)(5) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-20	At a minimum, the policies and procedures must address the role of the Provider/Supplier under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.	416.54(b)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-21	Communication plan: The Provider/Supplier must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years.	416.54.c Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-22	The communication plan must include names and contact information for Staff, Entities providing services under arrangement, Patients' physicians, Volunteers, and Other Provider/Suppliers within the same Medicare type.	416.54(c)(1) Standard 416.54(c)(1)(i) Standard 416.54(c)(1)(ii) Standard 416.54(c)(1)(iii) Standard 416.54(c)(1) Standard A	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
		B C		
5-D-23	The communication plan must include contact information for Federal, state, tribal, regional, and local emergency preparedness staff and Other sources of assistance.	416.54(c)(2) Standard 416.54(c)(2)(i) Standard 416.54(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-24	The communication plan must include primary and alternate means for communicating with Provider/Supplier's staff and Federal, State, tribal, regional, and local emergency management agencies.	416.54(c)(3) Standard 416.54(c)(3)(i) Standard 416.54(c)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-25	The communication plan must include a method for sharing information and medical documentation for patients under the Provider/Supplier's care, as necessary, with other health care providers to maintain the continuity of care.	416.54(c)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-26	The communication plan must include a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).	416.54(c)(5) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-27	The communication plan must include a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).	416.54(c)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-28	The communication plan must include a means of providing information about the Provider/Supplier's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.	416.54(c)(7) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-29	Training and testing: The Provider/Supplier must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, policies and procedures in standard 5-D-9, and the communication plan in standard 5-D-21. The training and testing program must be reviewed and updated at least every two (2) years.	416.54(d) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-30	The training program must consist of initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.	416.54(d)(1)(i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-31	The training program must provide emergency preparedness training at least every two (2) years.	416.54(d)(1)(iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-32	The training program must maintain documentation of all emergency preparedness training.	416.54(d)(1)(iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-33	The training program must demonstrate staff knowledge of emergency procedures.	416.54(d)(1)(iv) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-34	If the emergency preparedness policies and procedures are significantly updated, the Provider/Supplier must conduct training on the updated policies and procedures.	416.54.d.1.v Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-35	The Provider/Supplier must conduct exercises to test the emergency plan at least annually.	416.54(d)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-36	The Provider/Supplier must participate in a full-scale exercise that is community-based every two (2) years; or When a community based exercise is not accessible, conduct a facility-based functional exercise every two 2) years; or If the Provider/Supplier experiences an actual natural or man-made emergency that requires activation of the emergency plan, the Provider/Supplier is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.	416.54(d)(2)(1) Standard 416.54(d)(2)(i)(A) Standard 416.54(d)(2)(i)(B) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-D-37	The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise as required by standard 5-D-36 is conducted, that may include, but is not limited to the following: A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or B) A mock disaster drill; or C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.	416.54(d)(2) (ii) Standard 416.54(d)(2) (ii)(A) Standard 416.54(d)(2) (ii)(B) Standard 416.54(d)(2) (ii)(C) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-D-38	The Provider/Supplier must analyze the Provider/Supplier's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the Provider/Supplier's emergency plan, as needed.	416.54(d)(2) (iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: Emergency Preparedness Plan – Integrated Healthcare Systems				
5-E-1	The Provider/Supplier must analyze the Provider/Supplier's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the Provider/Supplier's emergency plan, as needed.	416.54(e) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-2	If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.	416.54(e)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-3	If elected, the unified and integrated emergency preparedness program must be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.	416.54(e)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-E-4	If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.	416.54(e)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-5	If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 5-D-4, 5-D-5, and 5-D-7.	416.54(e)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-6	If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 5-D-4, 5-D-5, 5-D-6, and 5-D-7.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
5-E-7	If elected, the unified and integrated emergency plan must also be based on and include a documented community-based risk assessment, utilizing an all-hazards approach.	416.54(e)(4) (i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-8	If elected, the unified and integrated emergency plan must also be based on and include a documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.	416.54(e)(4) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
5-E-9	If elected, the unified and integrated emergency preparedness program must include integrated policies and procedures that meet the requirements set forth in 5-D-9, a coordinated communication plan, and training and testing programs that meet the requirements in standards 5-D-21 and 5-D-29, respectively.	416.54(e)(5) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix Z	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 6: MEDICATIONS

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Medications				
6-A-1	The facility must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice and under the direction of an individual designated responsible for pharmaceutical services.	416.48 Condition A B C	**Interpretive Guidance:** Medication errors are the most reported type of medical error. They are preventable events that can result in serious patient harm (e.g., disability, death) and occur during any phase of the medication-use process (i.e., from procuring the medication to monitoring the patient after administration). Adherence to national standards of practice is critical. **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **AORN Guidelines in Practice: Medication Safety** https://aornjournal.onlinelibrary.wiley.com/doi/epdf/10.1002/aorn.14034 **USP 797 Key Changes (ashp.org)** **ASA Statement on Security of Medications in the Operating Room, 2023** https://www.asahq.org/standards-and-practice-parameters/statement-on-security-of-medications-in-the-operating-room	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA Safe Injection Guidelines for Needle and Syringe Use, 2022 https://issuu.com/aanapublishing/docs/8_-_safe_injection_guidelines_for_needle_and_syrin?fr=sNzEyZTU2NDAxMjU **American Society of Ophthalmic Registered Nurses (ASORN) Use of Multi-dose Medications** https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/ **Using Multidose Eyedrops in a Health Care Setting, 2014** https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216 **USP General Chapter Labeling: Expiration Date FAQs December 2023** https://go.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_gcl_au*MTE5NjEzMzM3OS4xNzA3NDE4MTA0*_ga*MTY4NDc2MjkyOS4xNzA3NDE4MTA1*_ga_DTGQ04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-A-2	Drugs must be prepared and administered according to established policies and acceptable standards of practice.	416.48(a) Standard A B C	**Interpretive Guidance:** Note: Per the USP, expiration dates must be formatted using the year (in a 4-digit format), the month, and, if applicable, the day, separated by hyphens or forward slashes in accordance with USP 700 Updates December 2023. Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for drug storage, the ASC is expected to follow the labelled conditions. **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **USP General Chapter Labeling: Expiration Date FAQs December 2023** go.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_gcl_au*MTE5NjEzMzM3OS4xNzA3NDE4MTA0*_ga*MTY4NDc2MjkyOS4xNzA3NDE4MTA1*_ga_DTGQ04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA.. **CDC Single-Dose or Multi-Dose** https://www.cdc.gov/injection-safety/media/pdfs/Injection-Safety-For-Healthcare-P.pdf	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC Safe Injection Practices https://www.cdc.gov/injection-safety/hcp/clinical-guidance/index.html **American Society of Ophthalmic Registered Nurses (ASORN) Use of Multi-dose Medications** https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/ **Using Multidose Eyedrops in a Health Care Setting, 2014** https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216 **USP General Chapter Labeling: Expiration Date FAQs December 2023** go.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_gcl_au*MTE5NjEzMzM3OS4xNzA3NDE4MTA0*_ga*MTY4NDc2MjkyOS4xNzA3NDE4MTA1*_ga_DTGQ04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA..	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-A-3	Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.	416.48(a)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
6-A-4	If there is an adverse reaction, it must be immediately reported to the physician responsible for the patient and must be documented in the patient's record.	416.48(a)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
6-A-5	Outdated medications are removed and destroyed in accordance with federal/national, state, provincial, and local pharmacy regulation.	A B C	**Interpretive Guidance:** Drug expiration dates reflect the time period during which the product is known to remain stable and maintain its integrity, which means it retains its strength, quality, and purity when it is stored according to its labeled storage conditions. Medications not stored within proper temperature settings may be considered expired for patient use. Some medications may require certain temperatures to maintain potency (i.e., muscle relaxants). The manufacturer's instructions for storage and use must be followed.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			For domestic programs: If medications are on backorder, the expiration may be extended based on the FDA extended use date: Search List of Extended Use Dates to Assist with Drug Shortages | FDA **Evaluating Compliance:** • Inspect and check for expired medications. • Check manufacturers' recommendations for accurate best use by date or expirations. If expired medications are observed, interview staff to determine if a procedure is in place to check expiration dates regularly. • Review related medication storage policies. • Interview staff. **Search List of Extended Use Dates to Assist with Drug Shortages | FDA**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-A-6	Medications are stored in a secured area away from patient and visitor access.		**Interpretive Guidance:** A secure environment is necessary for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled pharmaceutical agents used for elective and emergency care. A secure physical area assures the integrity of anesthesia machines and other equipment and materials. The security of medications, while maintaining rapid accessibility, in a secure anesthetizing location is essential for patient safety. The facility's policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and patient safety. Automated Dispensing Cabinets (ADCs) are a secure option for medication storage. They ensure locked storage and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification, so that they can only be accessed by authorized personnel. Medication carts, anesthesia carts, epidural carts, and other non-automated medication carts containing drugs and biologicals must be secured when not in use.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Because a secure anesthetizing location is a limited-access secure location, it is safe practice for anesthesia professionals to leave non-controlled* medications on the top of their anesthesia carts or anesthesia machines for brief periods (e.g., while going to a nearby holding area to bring a patient into the operating room). All syringes must be labeled with the drug's generic name and concentration (in units per mL). The date and time of preparation and the preparer's initials or name should also be included. For infusion bags containing pharmaceuticals for use in the practice of anesthesiology, the total volume of the bag and the generic name and amount of each added pharmaceutical should be the most prominently displayed information. The final concentration of each pharmaceutical in units per mL should also be displayed, as well as the date and time of preparation, the preparer's name or initials, and the patient's name. Vials and ampules: Medication containers intended for use in the practice of anesthesiology should display the generic name and concentration (as the total amount of medication in the container divided by the total volume) most prominently. Preferably, the concentration in units per mL is also displayed. 0Syringes and containers of medications intended	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			only for regional anesthesia shall be clearly marked as such. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia professionals dedicate full attention to their patients. This vulnerable period extends from the time the patient emerges from anesthesia until the anesthesia professional transfers care of the patient to recovery personnel. If drugs are locked up during this vulnerable period, provider access to drugs required for emergency patient care is obstructed. Requiring anesthesia professionals to divert attention from patients in order to lock non-controlled* medications in anesthesia carts during the period between emergence from anesthesia and transport of patients out of the operating room jeopardizes patient safety. Therefore, locking non-controlled medications at this point in the anesthetic is not required. It is necessary and safe practice for non-controlled medications to be set up for emergency cases (e.g., obstetrics, trauma). If this is a non-secure location, then medications must be made secure ("locked") by a tamper-evident device that can easily be broken by authorized persons. It is necessary and safe practice for emergency anesthesia drugs (e.g., dantrolene for the treatment of malignant hyperthermia) to be kept in a dedicated	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			emergency cart or cupboard and made secure ("locked") by a tamper-evident device. **Evaluating Compliance:** • While touring the facility, observe medication storage areas to determine the security of the medications and that medications are not accessible to patients and visitors. • Are medications stored in accordance with manufacturer's instruction? • Are the temperature of refrigerators and warmers maintained within the parameters of the medication stored inside? Is the facility able to demonstrate that the temperature of medication refrigerators and warmers are monitored at least daily or more frequently if necessary? • If a refrigerator or warmer is not within acceptable temperature parameters, is there documentation of action taken by the facility to correct the issue? • Review the contents of anesthesia carts. If non-controlled medications are left on the top of anesthesia carts or anesthesia machines, is this done for brief periods only (e.g., while going to a nearby holding area to bring a patient into the operating room or to the recovery area)? • Are all medications labeled with the generic name of the medication, concentration, date and time of preparation, and the name or initials of the preparer?	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Are emergency anesthesia drugs (e.g., dantrolene for the treatment of malignant hyperthermia) kept in a dedicated emergency cart or cupboard and made secure ("locked") by a tamper-evident device that can easily be broken by authorized persons? **Safe Medication Management at Ambulatory Surgery Centers - Ubaldi - 2019 - AORN Journal - Wiley Online Library** **ISMP Launches New Perioperative Medication Safety Guidelines | Institute For Safe Medication Practices** **ISMP Facility Endorsements** (Please note that QUAD A is an endorsing organization!) **ASA Statement on Security of Medications in the Operating Room, 2023** https://www.asahq.org/standards-and-practice-parameters/statement-on-security-of-medications-in-the-operating-room **AANA USP General Chapter 797, 2023** https://www.aana.com/practice/clinical-practice/clinical-practice-resources/usp-general-chapter/ **AANA Safe Injection Guidelines for Needle and Syringe Use, 2022**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			www.aana.com/PracticeManual. **AORN Guideline for Medication Safety, 2023** https://aornguidelines.org/guidelines/content?sectionid=173722338&view=book#173722338	
SUB-SECTION B: Intravenous Fluids				
6-B-1	Intravenous fluids such as Lactated Ringer's solution and/or normal saline are available in the facility, including intravenous (IV) administration sets, and various sizes of IV needles based on the patient population served.	A B C	**Interpretive Guidance:** • The intent is to ensure that IV fluids and IV supplies appropriate to the patient population are available. **Evaluating Compliance:** • Observe the facility. Are IV fluids appropriate to the patient population served, and are administration sets available?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION C: Blood and Blood Substitutes				
6-C-1	If blood is administered in the facility, a protocol is present that addresses: typing; cross- matching; checking; verification; who may administer blood; and, patient monitoring requirements.	A B C	**Interpretive Guidance:** "Type and screen" refers to pre-transfusion tests that include the determination of the client's ABO group, Rh type, and a screen for the detection of atypical antibodies. The individual administering the blood ensures that type and screen testing has been completed before initiating a blood transfusion and also uses this information during a two-person verification of a blood product before it is administered to a patient. **Evaluating Compliance:** • Review the facility protocol for blood administration. • Interview staff. • Does the clinical record contain documentation that the blood has been typed, cross-matched, checked, and verified? Is the professional administering the blood in concurrence with the facility protocol? Is the patient monitored in accordance with the facility protocol? • If blood is being administered during the survey, observe the process and determine if the process is consistent with the facility's policy and procedure.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-C-2	Blood and blood products must be administered only by physicians, anesthesia professionals, or registered nurses.	416.48(a)(2) Standard A B C	**Interpretive Guidance:** The intent is to ensure that blood and blood products are administered safely. **Evaluating Compliance:** • Review facility policy. • Interview staff. • During the clinical record review, determine who administered the blood. Is blood administered only by a physician, anesthesia professional, or registered nurse? • Observe transfusion practices if blood is being administered during the survey. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **Clinical Procedures for Safet Patient Care, 8.7 Transfusion of Blood and Blood Products, 2015** https://opentextbc.ca/clinicalskills/chapter/blood-and-blood-product-administration/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION D: Controlled Substances				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-D-1	All controlled substances are secured and locked under supervised access. Storage of controlled substances must be in accordance with applicable federal/national, state/provincial, and local regulations.	A B C	**Interpretive Guidance:** Controlled substances are stored in securely locked, substantially constructed cabinet. Locked drawers alone do not provide adequate security for the storage of controlled substances. **DEA § 1301.75 Physical security controls for practitioners.** (a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75 **Evaluating Compliance:** Review the storage of controlled substances to determine if secure and supervised access exists. **Federal Controlled Substances Act: Ordering and Recordkeeping** **DEA published manual**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Pharmacist's Manual An Informational Outline of the Controlled Substances Act **DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act** www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf **DEA Registration Q&A** https://deadiversion.usdoj.gov/faq/registration-faq.html **Narcotic Drugs: Handling and Documentation,2023** www.rn.org/courses/coursematerial-10004.pdf	
6-D-2	There is a dated controlled substance inventory and a control record that includes the use of controlled substances on individual patients. Such records must be kept in the form of a sequentially numbered, bound journal from which pages may not be removed, or in a tamper -proof, secure computer record consistent with state and federal law. This log must be kept in the facility.	A B C	**Interpretive Guidance:** There must be records of receipt and disposition of all controlled substances, including those brought into the facility by a contract anesthesia professional. The intent is to prevent diversion. The facility's policies and procedures should address the following: • Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs. • Records of the receipt and disposition of all controlled substances must be current and accurate.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Records to trace the movement of scheduled drugs throughout the facility. • The licensed healthcare professional who has been designated responsible for the facility's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled. • The record system, delineated in policies and procedures, tracks the movement of all controlled substances from the point of entry into the facility to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on controlled substances in a readily retrievable manner to facilitate the reconciliation of the receipt and disposition of all controlled substances. • All drug records are in order, and an account of all controlled substances is maintained, and any discrepancies in the count are reconciled promptly. • The facility's system is capable of readily identifying the loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion. • Pages are sequentially numbered and there is no evidence of page removal or other tampering.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Per the DEA-approved logbook, **professional** plastic spiral binding is acceptable. However, pages must be numbered sequentially so that it is apparent if a page or pages have been removed. • Logs are in a secure electronic or hard copy format. • Secure electronic logs do not need to be sequentially numbered. • If the facility is using Pyxis and an electronic clinical record (EMR), these constitute a "secure computer record" that contains all required information. In this situation, no additional written narcotic log is required. However, an end-of-shift narcotic count is still required. • The facility must house only one (1) DEA-compliant controlled substance log. Multiple versions are not acceptable. • The facility policies and procedures address the steps to be taken if drug diversion is identified. • If evidence of theft or diversion is identified, the facility must report this to the Drug Enforcement Administration (DEA) and local law enforcement, and state regulatory boards as required. **Evaluating Compliance:** If the facility uses controlled substances: • Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the records to determine that they trace the movement of controlled substances throughout the facility. • Determine if there is a system, delineated in policies and procedures, that tracks the movement of all controlled substances from the point of entry into the facility to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs. • Determine if the licensed health care professional who oversees the facility's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all controlled substances is maintained and periodically reconciled. • Is the facility's system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion? • Determine if facility policy and procedures minimize controlled substance diversion. • If evidence of theft or diversion is identified, has the facility reported this to the Drug Enforcement Administration (DEA) and local law enforcement, and state regulatory boards as required?	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Federal Controlled Substances Act: Ordering and Recordkeeping **DEA published manual** Pharmacist's Manual An Informational Outline of the Controlled Substances Act **DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act** www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf **DEA Registration Q&A** https://deadiversion.usdoj.gov/faq/registration-faq.html **Narcotic Drugs: Handling and Documentation,2023** www.rn.org/courses/coursematerial-10004.pdf **DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act** www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-D-3	All controlled substance transactions, including daily counts and wastes, require verification by two (2) licensed members of the team. (For facilities with only Schedule IV and V controlled substances, one (1) licensed and (1) authorized member of the operating room team may document verification of daily counts and wastes.) These verifications must be completed on any day that the facility is open and/or controlled substances are administered, and in compliance with federal/national, provincial, state, and local regulations. The facility must develop a policy detailing how unlicensed authorized individuals are authorized, if applicable.	A B C	**Interpretive Guidance:** The intent is to prevent diversion of controlled substances. RNs, LPNs, and physicians are licensed personnel. Authorized personnel include other members of the operative team designated by the facility per its policy. Two (2) licensed professionals are preferred; however, it is recognized that smaller facilities may not have two licensed professionals present in the facility, An inventory count is necessary when using a hard copy or an electronic controlled substance log, including a medication dispensing machine such as a pyxis **Evaluating Compliance:** • Review facility policy for the appointment of unlicensed authorized individuals. • Review the controlled substance transactions in the log, including daily counts and waste, to determine if all transactions have been verified by two (2) licensed personnel or in Class A facilities using only Schedule IV and V controlled substances (1) licensed and (1) authorized personnel. • For any noted discrepancies, interview staff and review related documentation to determine what action was taken to resolve the discrepancy.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• If evidence of theft or diversion is identified, has the facility reported this to the Drug Enforcement Administration (DEA) and law enforcement, and state regulatory boards as required? **Federal Controlled Substances Act: Ordering and Recordkeeping** **Pharmacist's Manual An Informational Outline of the Controlled Substances Act** **DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act** www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf **DEA Registration Q&A** https://deadiversion.usdoj.gov/faq/registration-faq.html **Narcotic Drugs: Handling and Documentation,2023** www.rn.org/courses/coursematerial-10004.pdf **DEA Theft/Loss Reporting** https://www.deadiversion.usdoj.gov/21cfr_reports/theft/theft-loss.html	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-D-4	There must be a record of receipt and disposition of all controlled substances. Records must be maintained for a minimum of three (3) years.	A B C	**Interpretive Guidance:** The intent is to prevent diversion of controlled substances. **Evaluating Compliance:** • Review facility records to determine if records of receipt and disposition of all controlled substances are complete. • Review related facility policies and procedures. • Review the facility's DEA form 222. **Federal Controlled Substances Act: Ordering and Recordkeeping** **Pharmacist's Manual An Informational Outline of the Controlled Substances Act** **DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act** www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf **DEA Registration Q&A** https://deadiversion.usdoj.gov/faq/registration-faq.html **Narcotic Drugs: Handling and Documentation,2023** www.rn.org/courses/coursematerial-10004.pdf	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-D-5	If contracted anesthesia professionals bring controlled substances into the facility, the facility must ensure compliance with all QUAD A standards, local, state, and federal laws and DEA regulations.	A B C	**Interpretive Guidance:** If a contracted anesthesia professional is responsible for narcotic procurement and administration, the anesthesia professional must maintain a DEA registration at the facility location. In the event narcotic supplies are maintained in a central location, each facility's supply must be designated under the address of the facility to the DEA. Duplicate copies of all records, including controlled substance receipt confirmation and patient administration records, must be available in the facility and the central location. Storage of the controlled substance must be in accordance with applicable federal, state, and local regulations. If a contracted anesthesia professional brings narcotics into the facility, it is the facility's responsibility to track, log, and count them. The facility also has the responsibility to ensure that all QUAD A requirements are met whenever anything, e.g., supplies, or equipment, is brought into the facility. A surveyor may ask the facility staff to call an anesthesia professional in and be present during the facility's accreditation survey. All supplies routinely transported to the facility for use in patient care should be present during an accreditation survey so there can be an evaluation of the anesthesia equipment, and drugs used.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			The transport of these controlled substances must follow DEA and any other local, state, or federal laws of ordering and transport of medications. When anesthesia services are provided by an outside anesthesia group in a QUAD A accredited facility, these services must be performed in accordance with the terms of a written contract. The contract must specify that the accredited facility retains professional and administrative responsibility for, and control and supervision of the anesthesia services. Contracted services personnel are part of the accredited facility. QUAD A standards and the facility's policies and procedures must apply to all services provided by that facility, including those provided through a contractual agreement. **Evaluating Compliance:** • Observe the practices of contract anesthesia professionals. Are practices provided in accordance with facility policies and procedures, and QUAD A requirements? • Does the contract anesthesia professional responsible for narcotic procurement and administration maintain a DEA registration at the facility location? • Are narcotic supplies brought in by a contracted anesthesia professional maintained in a central location? Is the	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			facility's supply designated under the address of the facility to the DEA? Are duplicate copies of all records, including controlled substance receipt confirmation and patient administration records, available in the facility and the central location. Is storage of the controlled substance in accordance with applicable federal, state, and local regulations? • Does the facility track, log, and count these narcotics? • Are all supplies routinely transported to the facility for use in patient care present during the survey? Conduct an evaluation of the anesthesia equipment, and drugs used to determine compliance. • Review the written contract with the contracted anesthesia professional to determine if services are performed in accordance with the terms of the written contract. Does the contract specify that the accredited facility retains professional and administrative responsibility for and control and supervision of the anesthesia services? **Federal Controlled Substances Act: Ordering and Recordkeeping** **DEA published manual** Pharmacist's Manual An Informational Outline of the Controlled Substances Act	

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			DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf **DEA Registration Q&A** https://deadiversion.usdoj.gov/faq/registration-faq.html **Narcotic Drugs: Handling and Documentation.2023** www.rn.org/courses/coursematerial-10004.pdf	
SUB-SECTION E: ACLS/PALS Algorithm				
6-E-1	A complete and current copy of the current ACLS and/or PALS Algorithm, as appropriate for the patient population served in the facility, must be available on the emergency cart.	A B C	**Interpretive Guidance:** The intent is to ensure necessary drugs are available in sufficient quantities to run a full code based on the ACLS and/or PALS algorithm. **Evaluating Compliance:** Determine if a current copy of the ACLS and/or PALS algorithm is available on the emergency cart. **Crash cart supply & equipment checklist: Essential guide (acls.net)** **2024 AHA Algorithms** https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines/algorithms **AHA Emergency Cardiovascular Care**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines/algorithms **2021 – 2025 AHA ACLS Guideline Changes** https://acls-algorithms.com/2021-aha-acls-guideline-changes/	
6-E-4	The following medication must be available in the facility at all times as required by the current ACLS/PALS algorithm: Adenosine Epinephrine (1:10,000 solution, 1 mg per 10 ml) Anti-Hypertensives Lidocaine (2% plain) Atropine Nitroglycerin (sublingual tablets or spray) Narcan Intravenous corticosteroids (e.g., dexamethasone)	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The amounts are sufficient to run a full code. The correct lidocaine to be used in a patient's cardiac emergency is lidocaine 2% HCL injection. 100mg/5 ml. The box also indicates "I.V. for Cardiac Arrhythmias" and generally appears in a red box. Plain Lidocaine 1% or 2% for injection is used as a local anesthetic. Plain Lidocaine for injections is **NOT** a substitute for Lidocaine HCl 2% as a required ACLS medication. Bupivacaine is also **NOT** a substitute for Lidocaine HCL 2% used in ACLS. If used during a patient's cardiac emergency, plain Lidocaine or Bupivacaine can cause ***SIGNIFICANT*** patient harm. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration and quantity of these medications are consistent with ACLS/PALS algorithms.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AHA Emergency Cardiovascular Care https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines/algorithms **2021 – 2025 AHA ACLS Guideline Changes** https://acls-algorithms.com/2021-aha-acls-guideline-changes/	
6-E-5	There must be a written protocol for cardiopulmonary resuscitation (CPR). This protocol must include the provision for annual drills, staff training upon hire and annually, drill documentation, and retention of documentation for at least three (3) years	A B C	**Interpretive Guidance:** The intent is to ensure that staff are prepared and knowledgeable in required roles and activities when cardiopulmonary resuscitation is needed. This protocol should include the various roles, who must respond, how CPR will be implemented, and individuals who should be called if assistance is required to maintain patient safety. The protocol is reviewed and tested annually and updated as necessary. Applicable staff must be trained upon hire and annually on the CPR protocol./Code Blue drill **Evaluating Compliance:** • Interview staff to assess knowledge of the CPR protocol and other medical emergency protocols. • Review the protocols for all required elements and evidence that the protocol is reviewed and revised annually. **Algorithms | American Heart Association CPR & First Aid**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			The Impact of Mock Code Simulation on the Resuscitation Practice and Patient Outcome for Children With Cardiopulmonary Arrest - PubMed (nih.gov) **Mock Drill Checklist (Code Blue) (16737) | PDF (scribd.com)**	
SUB-SECTION F: EMERGENCY MEDICATIONS				
6-F-1	All emergency medications as noted must be available and in the facility at all times. Licensed personnel in the facility must know their location.	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. Licensed personnel are aware of their location. **Evaluating Compliance:** • Review emergency medications and interview clinical staff to determine if all are always available in the facility. • Are they available in sufficient quantities based on the population served? • Interview clinical staff and ask them to point out the location of emergency medications to determine their awareness of their location.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-2	The following medication must be available in the facility at all times: IV Antihistamines (e.g. Diphenhydramine).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the patient population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
6-F-3	The following medication must be available in the facility at all times: Short-acting beta-blocker (eg, esmolol or labetalol).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the patient population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-4	The following medication must be available in the facility at all times: Neuromuscular blocking agents including non-depolarizing agents such as rocuronium or depolarizing agents such as succinylcholine.	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. Succinylcholine can be stored outside the refrigerator. However, based on the literature this requires extra monitoring due to degradation of the drug at room temperature and shorter shelf-life. The best practice is to store succinylcholine in the refrigerator at 4 degrees Celsius. If a 10% loss of potency is considered acceptable, then the 20 and 50 mg/ml succinylcholine solutions can be stored in emergency resuscitation carts at room temperature for 8.3 and 4.8 months, respectively; if kept at room temperature, the facility is expected to label the vial with the new expiration date. Rocuronium bromide should be stored in a refrigerator, 2° to 8°C (36° to 46°F). DO NOT FREEZE. Upon removal from refrigeration to room temperature storage conditions (25°C/77°F), use rocuronium bromide within 60 days. Use opened vials of rocuronium bromide within 30 days. When medications are stored in a refrigerator, the facility must monitor the refrigerator temperature and document it daily when the facility is open and providing patient services.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Review the facility's medication storage policies and procedures for succinylcholine and or rocuronium bromide for completeness and appropriateness. • Interview staff. • Determine how succinylcholine and/or rocuronium bromide are stored. If stored at room temperature, are the vials labeled appropriately with the new expiration date? Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the patient population served. • Review refrigerator temperature monitoring logs. **Stability of Succinylcholine Solutions Stored at Room Temperature** www.researchgate.net/publication/6456254_Stability_of_succinylcholine_solutions_stored_at_room_temperature_studied_by_nuclear_magnetic_resonance_spectroscopy **Succinylcholine Chloride, 2023** https://www.ncbi.nlm.nih.gov/books/NBK499984/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-5	The following medication must be available in the facility at all times: If a Benzodiazepine is used in the facility, a reversal agent must be available (e.g. Mazicon™, Flumazenil).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. Reversal agents are defined as any drug used to reverse the effects of anesthetics, narcotics, or potentially toxic agents. **Evaluating Compliance:** Review the emergency medications to determine if a reversal agent is available in the facility at all times. Is it present in sufficient quantities based on the population served? **National Library of Medicine, Reversal agents in anaesthesia and critical care, 2015** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4645356/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-7	There must be a written protocol for cardiopulmonary resuscitation (CPR). This protocol must include the provision for annual drills, staff training upon hire and annually, drill documentation, and retention of documentation for at least three (3) years.	A B C	**Interpretive Guidance:** The intent is to ensure that staff are prepared and knowledgeable in required roles and activities when cardiopulmonary resuscitation is needed. This protocol should include the various roles, who must respond, how CPR will be implemented and individuals who should be called if assistance is required to maintain patient safety. Applicable staff must be trained upon hire and annually on the CPR protocol. **Evaluating Compliance:** • Interview staff to assess knowledge of the CPR protocol. • Review the protocol for all required elements and evidence that the protocol is reviewed and revised annually. • •Review applicable personnel records to determine the appropriate training has been provided initially upon hire and annually thereafter, and any time updates occur. **Algorithms | American Heart Association CPR & First Aid** **The Impact of Mock Code Simulation on the Resuscitation Practice and Patient Outcome for**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Children With Cardiopulmonary Arrest - PubMed (nih.gov) **Mock Drill Checklist (Code Blue) (16737) | PDF (scribd.com)** **2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Parts 1 - 6** https://www.ahajournals.org/toc/circ/142/16_suppl_2/6d2	
6-F-8	The following medication must be available in the facility at all times: Bronchospasm-arresting medication (inhaled beta-agonist, eg albuterol).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are available in sufficient quantities based on the population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-9	The following medication must be available in the facility at all times: Anti-hypertensives.	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
6-F-10	The following medication must be available in the facility at all times: Seizure arresting medication (a benzodiazepine, e.g. Midazolam).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities of first-line seizure arresting medications are sufficient based on the population served. First-line seizure-arresting medications are fast-acting medications that include lorazepam, diazepam, clonazepam, midazolam (IV or nasal spray), and phenobarbital. Phenytoin is **not** considered a first-line seizure-arresting medication; it is a second-line medication used for established status epilepticus (20 – 40 minutes). It is often not possible to take a medication by mouth during a seizure, and the medications used	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			for emergency management of seizures are available in forms that can be injected into a muscle (IM), administered intravenously (IV, in a vein), used as a nasal spray, or administered rectally. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the patient population served. **Rescue Medications for Seizures** https://www.verywellhealth.com/medications-used-for-seizure-emergencies-5100921 **Seizure Rescue Therapies** https://www.epilepsy.com/treatment/seizure-rescue-therapies#What-are- **Medical management of status epilepticus: Emergency room to intensive care unit** https://www.seizure-journal.com/article/S1059-1311(19)30204-3/fulltext	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-11	The following medication must be available in the facility at all times: Intravenous corticosteroids (eg, dexamethasone).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review emergency medications to determine if the type, concentration, and quantity of these medications are available in sufficient quantities based on the patient population served.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
6-F-12	Facilities administering regional or tumescent anesthesia containing bupivacaine must always have 20% lipid emulsion available.	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. **Evaluating Compliance:** Review the emergency medications to determine if 20% lipid emulsion is always available in the facility. Is it present in quantities appropriate to the patient population served? **Internet Book of Critical Care (IBCC) Local Anesthetic Systemic Toxicity (LAST), 2021** https://emcrit.org/ibcc/last/	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-F-13	The following medication must be available in the facility at all times: A narcotic reversal agent (e.g., naloxone, nalmefene).	A B C	**Interpretive Guidance:** The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served. Reversal agents are defined as any drug used to reverse the effects of anesthetics, narcotics, or potentially toxic agents. **Evaluating Compliance:** Review the emergency medications to determine if a narcotic reversal agent is always available in the facility. Are the quantities sufficient for the population served?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION G: Malignant Hyperthermia				
6-G-1	If the depolarizing muscle relaxant succinylcholine is present only for use in emergency airway rescue, the facility must document a protocol to manage the possibility of malignant hyperthermia (MH) following its use, and staff training must occur on hire and then annually. In this instance, MH-related components as outlined in standards 6-G-5 through 6-G-11 are **not** required. Section 6-G does **not** apply if anesthetic gases and polarizing agents that trigger malignant hyperthermia are not present in the facility at all.	C	**Interpretive Guidance:** Malignant hypertension (MH) is a hypertensive emergency with rapid disease progression and poor prognosis. Facilities choosing polarizing medications Rocuronium as their neuroblocking agent for emergency airway rescue are **not** required to follow standards in section 6-G but are required to have the current MHAUS algorithm present on their emergency cart. (See comment on the algorithm) **Malignant Hyperthermia Requirements for Surgical and Procedural Programs**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
	If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used or are present in the facility **standards 6-G-5 through 6-G-11 apply.**		• **Class A and B - MH standards do not apply.** • **Class C Triggering Agents not present** - MH standards do not apply **with the exception** of the need for a protocol, MH algorithm present on the emergency cart, and annual staff training • **Class C Triggering Agents present -** All MH Standards apply, including an MH drill. • **Class C Triggering agents present only for emergency use –** a documented protocol to manage the possibility of malignant hyperthermia (MH) following its use, and staff training are required. **Evaluating Compliance:** • Determine through observation and staff interviews if triggering agents such as isoflurane, sevoflurane, desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used or are present in the facility. If present, evaluate compliance with applicable standards. • Review the facility MH protocol. • Review the facility protocol for managing MH when succinylcholine is present only for use in emergency airway rescue. • Interview members of the surgical team, • Review personnel files to determine if training has occurred upon hire and then annually.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA Malignant Hyperthermia https://www.aana.com/practice/clinical-practice/clinical-practice-resources/malignant-hyperthermia/ **AORN Guidelines Malignant Hyperthermia** https://aornguidelines.org/glance/content?gbosid=483811 **AORN Competency Verification Tool: Malignant Hyperthermia - RN** https://aornguidelines.org/tool/content?gbosid=396610 **MHAUS Recommendations for Managing an MH Crisis** https://www.mhaus.org/healthcare-professionals/	
6-G-2	Adequate screening for MH risk must be documented, that includes but is not limited to a family history of unexpected death(s) following general anesthesia or exercise; a family or personal history of MH, a muscle or neuromuscular disorder, high temperature following exercise; a personal history of muscle spasm, dark or chocolate colored urine, or unanticipated fever immediately following anesthesia or serious exercise.	C	**Interpretive Guidance:** The intent is to assess and minimize the risk of an MH crisis. If a patient is identified as a risk for MH or is considered to be susceptible to MH, the MHAUS precaution recommendations must be followed. This standard applies to all class C facilities regardless of the presence of a triggering agent in the facility. **Evaluating Compliance:** • Review the facility's MH risk assessment process. Does the screening process include the required elements?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the facility protocol, interview clinical staff, and review documentation of the completion and results of the assessment in the clinical records. **AORN Malignant Hyperthermia** https://aornguidelines.org/glance/content?gbosid=483811 **MHAUS Frequently Asked Questions, 2024** https://www.mhaus.org/faqs **MHAUS Recommendations for Managing an MH Crisis, 2024** https://www.mhaus.org/healthcare-professionals/	
6-G-5	If a facility uses depolarizing agents, MH crisis management must be covered in annual staff training. All clinical staff (including contracted healthcare professionals) must be trained. Annual drills are conducted for MH crisis and management including actual dilution of at least one vial of actual Dantrolene (expired OK). Staff should be assigned roles prior to drills and a written protocol outlining those personnel and their roles is on file. Documentation of drills is required.	C	**Interpretive Guidance:** The intent is for all clinical staff to be familiar with the management of MH, the administration of Dantrolene/Ryanodex, and their assigned roles, which are key to successful outcomes. Annual drills are required if triggering agents are available in the facility. However, annual drills are **not** required if a triggering agent is on-site for emergency use only. **Evaluating Compliance:** • Review the facility protocol for MH drills. • Interview clinical staff regarding their role in an MH crisis and management.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Are annual drills conducted? Is there documentation available to demonstrate that drills are conducted and identify staff who participated in the drill? • Determine if the actual dilution of at least one (1) vial of (expired) Dantrolene occurred during the drills. • Review personnel files, including contracted healthcare professionals, to determine if the annual training requirement has been met. **AORN Malignant Hyperthermia** https://aornguidelines.org/glance/content?gbosid=483811 **MHAUS Recommendations for Managing an MH Crisis** https://www.mhaus.org/healthcare-professionals/ **MH Crisis Hotline** https://www.mhaus.org/healthcare-professionals/ **1-800-644-9737** Be prepared to give your name, number, facility, and email.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-G-6	If a facility uses depolarizing agents, a supply of sterile water for injection USP (without a bacteriostatic agent) is available to mix with dantrolene before injection (i.e. 60ml/vial for Dantrium® and Revonto®, 5ml/vial for Ryanodex®).	C	**Interpretive Guidance:** All drugs and supplies necessary to manage an MH crisis must be readily accessible to support a positive patient outcome. **Evaluating Compliance:** • Verify that an adequate supply of sterile water for injection is available to mix with Dantrolene/Ryanodex prior to injection as defined in the standard. • A vial of Dantrolene requires 60 ml of sterile water/vial as a diluent. A minimum supply of 12 vials requires 720 ml of diluent. • A vial of Ryanodex requires 5 ml of sterile water/vial as a diluent. A minimum of 1 vial requires 5 ml of diluent.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
6-G-7	If a facility uses depolarizing agents, a minimum of 4 ampoules, 50cc's each, of sodium bicarbonate (NaHCO3).	C	**Interpretive Guidance:** All drugs and supplies necessary to manage an MH crisis must be readily accessible to support a positive patient outcome. **Evaluating Compliance:** Determine if the minimum supply of four (4) ampules of 50 cc's NaHCO3 is available in the facility.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
6-G-8	If a facility uses depolarizing agents, a minimum supply of dantrolene/Ryanodex should be stocked to treat a patient of average weight (approximately 70kg) with an initial dose: Dantrium®/Revonto® - 12 vials (20 mg/vial) Ryanodex® - 1 vial (250 mg/vial).	C	**Interpretive Guidance:** All drugs and supplies necessary to manage an MH crisis must be readily accessible to support a positive patient outcome. Readily accessible in this instance means the facility is able to administer Dantrolene/Ryanodex within 10 minutes of the first sign of MH. **Evaluating Compliance:** Determine if a minimal supply of Dantrolene (12 vials) /Ryanodex (1 vial) is available in the facility.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
6-G-9	If a facility uses depolarizing agents, an additional* supply of dantrolene/Ryanodex and diluents are stored in the facility, or the facility has a written agreement with another source that will provide additional* dantrolene/Ryanodex and diluents on a STAT basis within 10 minutes for continued treatment and stabilization of a patient experiencing a MH episode. *Additional supply of dantrolene is defined as: Dantrium®/Revonto® - 24 vials (20 mg/vial) Ryanodex® - 2 vial (250 mg/vial)	C	**Interpretive Guidance:** All drugs and supplies necessary to manage an MH crisis must be readily accessible to support a positive patient outcome. Additional vials of Dantrolene/Ryanodex and diluents are available within ten (10) minutes either on-site or via an agreement with another source. **Evaluating Compliance:** • Determine the availability of an adequate additional supply of Dantrolene/Ryanodex. If the facility has a written agreement with another source that will provide additional medication within ten (10) minutes, review the written agreement. • Interview staff to determine if the ability of the outside source to provide additional Dantrolene/Ryanodex and diluents is tested.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Request that the outside source be contacted and request that they provide the additional medications and diluents. Time the process to determine if the 10-minute timeframe is met. **MHAUS Recommendations** https://www.mhaus.org/healthcare-professionals/mhaus-recommendations/	
6-G-10	If a facility uses depolarizing agents, flow sheets for any MH intervention as well as forms to rapidly communicate the progress of intervention with receiving facilities are on the emergency cart, and the facility must document and report any "adverse metabolic or musculoskeletal reaction to anesthesia". This documentation must be transportable with the patient when transferred to the receiving facility.	C	**Interpretive Guidance:** MH interventions are consistently timed, dated, and documented clearly to facilitate rapid communication with the receiving facility. Reporting an MH crisis to the North American Malignant Hyperthermia Registry (NSMHR) is encouraged but not required. **Evaluating Compliance:** • Review facility protocols for documentation. • Review facility flowsheets for MH. Are these flowsheets located on the emergency cart? Are all interventions documented on the flowsheet? Does the flowsheet and any other forms clearly and rapidly communicate the patient status and the progress of interventions to the receiving facility? • Are adverse metabolic or musculoskeletal reactions to anesthesia" documented and reported to the receiving facility?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Is documentation transportable to the receiving facility? • Does the facility maintain copies of all related documentation in the patient's clinical record? **NSHHR Reporting** https://anest.ufl.edu/namhr/namhr-report-forms/	
6-G-11	Facilities must have a policy for MH transfer including EMS 911 transport to a facility capable of ongoing treatment located within a reasonable distance. A healthcare professional with the ability to continue MH treatment must accompany the patient during transport and provide a report to the receiving facility staff.	C	**Interpretive Guidance:** A formal transfer agreement is in place between the facility and the receiving hospital. Safe and timely patient transport and transfer of care to a facility capable of ongoing treatment located within a reasonable distance of the facility is necessary. A competent licensed healthcare professional with the ability to continue MH treatment accompanies the patient during transport and provides a report to the receiving facility to facilitate continuity of patient care. Detailed communication of patient status to the receiving hospital staff must occur both prior to transport and at the time of arrival at the receiving hospital. **Evaluating Compliance:** • Review the facility policy and written agreement between the facility and the receiving hospital. Is the receiving facility located within a reasonable distance? Is a licensed healthcare professional with the ability to continue MH treatment required to accompany the patient during EMS transport and provide a report to	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			the receiving facility staff? Is the patient's status and ongoing treatment documented during transport? • Is there evidence that the patient's status and ongoing MH treatment are communicated to the receiving facility staff both prior to transport and at the time of arrival at the receiving facility?	

SECTION 7: INFECTION CONTROL

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Infection Control				
7-A-1	The facility must maintain an infection control program that seeks to minimize infections and communicable diseases.	416.51 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **Perioperative Standards & Recommended Practices (AORN)** **CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, 2024** https://www.cdc.gov/infection-control/hcp/core-practices/index.html	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC Standard Precautions for All Patient Care, 2024 https://www.cdc.gov/infection-control/hcp/basics/standard-precautions.html?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html **FDA Personal Protective Equipment for Infection Control, 2020** https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control **WHO Standard Precautions for the Prevention and Control of Infections** https://iris.who.int/bitstream/handle/10665/356855/WHO-UHL-IHS-IPC-2022.1-eng.pdf?sequence=1	
7-A-2	The facility must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.	416.51(b) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-A-3	The Infection Control program is under the direction of a designated and qualified professional who has training in infection control;	416.51(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
7-A-4	The Infection Control program is an integral part of the facility's quality assessment and performance improvement program.	416.51(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
7-A-5	The Infection Control program is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.	416.51(b)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-A-6	The infection control and prevention program must include documentation that the facility has considered, selected, and implemented nationally recognized infection control guidelines.	416.51(b) Standard A B C	**Interpretive Guidance:** The intent is to reduce the risk of infection. Implementation of nationally recognized guidelines and standards of practice for infection prevention and control practices is essential to providing safe and high-quality patient care across all settings where healthcare is delivered. **Evaluating Compliance:** Review the infection and prevention program to determine which nationally recognized infection control guidelines the facility has considered, selected, and implemented nationally recognized infection control guidelines. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
7-A-7	Appropriate scrub facilities are provided for the operating room staff consistent with current CDC guidelines for hand hygiene and surgical scrub.	A B C	**Interpretive Guidance:** The intent is to minimize the risk of infection. The surgical scrub is an important procedure required to reduce the risk of contamination by microorganisms during operative procedures. The surgical scrub involves first decontaminating the hands, then donning a sterile surgical gown and pair of sterile gloves.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Are supplies necessary for adherence to hand hygiene and surgical scrub readily accessible in all areas where patient care is being delivered? • Observe staff performing hand hygiene and the surgical scrub. **Note:** Performing the surgical hand scrub using a brush is no longer recommended. Scrubbing with a brush may damage the skin and increase the number of bacteria shedding from the hands. **World Health Organization (WHO)** **Centers for Disease Control and Prevention (CDC)** **Hand Hygiene | AORN eGuidelines+ (aornguidelines.org)**	
7-A-10	The facility's policies address operating/procedure room attire This includes scrub suits, caps or hair covers, gloves, operative gowns, masks, eye protection, and all other appropriate attire based on the procedure being conducted.	A B C	**Interpretive Guidance:** The intent is to minimize the risk of infection. The appropriate use of surgical attire is essential to preventing the transmission of pathogens and protecting staff. The goal of using the proper surgical attire is to reduce microbial contamination throughout the continuum of care in the surgical suite to prevent surgical site infections. The proper surgical attire should be worn in the semi-restricted and restricted areas of the facility.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Surgical practitioners working in the operating room include the following attire for the purpose of self-protection: disposable surgical caps; scrub trousers and tops; jackets; disposable shoe covers; surgical clogs or shoes; and surgical masks. Personal protective equipment (PPE), which protects staff from cross-infection or cross-contamination, includes gowns, gloves, masks, aprons, eye protection and disposable, fluid-resistant shoe covers. Facility policies and procedures usually identify the need to wear PPE during surgical procedures, and so normally certain items of PPE would always be used during surgical cases. All surgical practitioners working in the operating room have the authority and responsibility to monitor proper surgical attire compliance in case staff do not wear the correct attire or PPE. Any issues that arise must be corrected immediately. Wearing scrub attire that is laundered at a healthcare–accredited laundry facility or at the facility in accordance with state regulatory requirements and nationally recognized guidelines and standards of care provides control of the laundering process and helps ensure that effective laundering standards have been met. Home laundering is not acceptable. Home laundering is not monitored for quality, consistency, or safety. Home washing machines may not have the adjustable parameters or controls required to achieve the necessary thermal measures (eg, water	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			temperature); mechanical measures (eg, agitation); or chemical measures (eg, capacity for additives to neutralize the alkalinity of the water, soap, or detergent) to reduce microbial levels in soiled scrub attire. Scrubs worn outside the facility **may not** be used in the operating/procedure room. Scrub attire should be removed before leaving the facility. Changing out of scrub attire into street clothes when leaving the building reduces the potential for healthcare workers to transport pathogenic microorganisms from the facility or healthcare organization into the home or community. **Evaluating Compliance:** • Review the facility's surgical attire policies and procedures. Are they consistent with nationally recognized guidelines and standards of practice? • If surgical attire is laundered in-house, is laundering consistent with nationally recognized guidelines and standards of care? • Interview staff regarding surgical attire practices. • Observe clinical practice to determine if surgical attire is used in accordance with the facility's policies and procedures. • Are scrubs worn outside the facility also used in the operating/procedure room?	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AORN eGuidelines, Surgical Attire, 2024 https://aornguidelines.org/guidelines/content?sectionid=245923790&view=book#245923796 **AORN Surgical Do's and Don'ts, 2019** https://www.infectioncontrolresults.com/aorn-surgical-attire-dos-and-donts **CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, 2024** https://www.cdc.gov/infection-control/hcp/core-practices/index.html **CDC Laundry and Bedding, 2003** https://www.cdc.gov/infection-control/hcp/environmental-control/laundry-bedding.html **Operating Theatre Attire and Personal Protective Equipment, 2016** https://onlinelibrary.wiley.com/doi/10.1002/9781119548935.ch6	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-A-11	A sterile field is used during all operations and procedures, as applicable.	A B C	**Interpretive Guidance:** The intent is to minimize the risk of infection. Creating and maintaining a sterile field is foundational to aseptic technique and encompasses practice standards that are performed immediately prior to and during a procedure to reduce the risk of infection. **Evaluating Compliance:** Observe a procedure to determine if a sterile field is established and maintained throughout the procedure. Interview staff to determine if a sterile field is used for all procedures.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Hand Hygiene				
7-B-1	Hand hygiene is performed in accordance with current nationally recognized and/or WHO guidelines and standards of practice. Periodic hand hygiene auditing must be a part of the facility's quality activities. For surgical/procedural facilities: Scrub facilities are provided for the operating room staff. Scrub products (as appropriate), soap, and alcohol cleansers are provided for the operating room staff, consistent with current adopted guidelines and standards of practice for hand hygiene.	A B C	**Interpretive Guidance:** The intent is to minimize the risk of infection. Surgical hand antisepsis is the primary line of defense to protect the patient from pathogens on the hands of perioperative team members. Healthcare institutions conduct hand hygiene audits to ensure adherence to hand hygiene protocols. These audits are critical tools for assessing compliance, identifying areas for improvement, and ultimately enhancing patient safety. They are also great projects that can be incorporated into your facility's Quality Assurance and Performance	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Improvement (QAPI) program and Program Evaluation. A hand hygiene audit involves systematic and unannounced observation and recording of hand hygiene practices based on predefined criteria. These criteria often align with guidelines set forth by leading health organizations, such as the World Health Organization (WHO) or the Centers for Disease Control and Prevention (CDC). The primary goal of these audits is not to penalize facility staff but to provide constructive feedback and educational support to improve hand hygiene practices. The process of a hand hygiene audit typically involves several key steps. Initially, a team of trained observers is established. These individuals are responsible for monitoring hand hygiene practices within the facility setting. The observers discreetly record hand hygiene actions, noting whether healthcare workers perform hand hygiene at the appropriate times. This may include before touching a patient, before clean/aseptic procedures, after body fluid exposure/risk, after touching a patient, and after touching the patient's surroundings. The data collected during the audit is then analyzed to determine compliance rates. This analysis provides valuable insights into the hand hygiene	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			practices of facility staff and identifies patterns or trends that may require attention. For instance, the audit may reveal that compliance is lower during certain times of the day or before performing a task. Such findings are essential for effectively targeting interventions and training programs. Following the analysis, the results of the hand hygiene audit are shared with the facility staff. This feedback is crucial for fostering a culture of continuous improvement. During feedback sessions, facility staff have the opportunity to discuss barriers to hand hygiene compliance and brainstorm solutions. Moreover, these sessions can serve as educational opportunities, reinforcing the reasons behind hand hygiene protocols and demonstrating proper hand hygiene techniques. Hand hygiene audits are a vital component of infection prevention and control programs in QUAD A accredited facilities. They provide a structured means of assessing hand hygiene practices, identifying areas for improvement, and fostering a culture of safety. They are great QAPI projects whose outcomes can be captured in QAPI program evaluations and Program Evaluations. Through diligent efforts to conduct and act upon the findings of hand hygiene audits, your facility can significantly reduce the transmission of infectious diseases and protect the health and well-being of your patients and staff.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			If hand sanitizer is decanted from one container to another, the re-filled container must be labeled with the contents and contain and an expiration date. **Evaluating Compliance:** • Review the facility's policies and procedures. Are they consistent with the current adopted nationally recognized guidelines and standards of practice adopted by the facility? • Interview staff. Are they knowledgeable of hand hygiene and surgical scrub policies and procedures? • Are surgical scrub products, soap, and alcohol-based hand rubs readily accessible to the operating room staff consistent with current CDC and WHO guidelines for hand hygiene? • Is the hand scrub sink located in the semi-restricted areas near the entrance to the OR or procedure room? • Hand wash sinks must be separate from sinks used to clean dirty instruments. Does the facility have separate sinks for these purposes? • Observe practice. **AORN e Guidelines for Hand Hygiene** https://aornjournal.onlinelibrary.wiley.com/doi/abs/10.1002/aorn.13964	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Clinical Safety: Hand Hygiene for Healthcare Workers https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html **CONSENSUS RECOMMENDATIONS - WHO Guidelines on Hand Hygiene in Health Care - NCBI Bookshelf (nih.gov)** https://www.ncbi.nlm.nih.gov/books/NBK144035/#:~:text=When%20performing%20surgical%20hand%20antisepsis,are%20not%20necessary%20(IB) **World Health Organization (WHO)** https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene **Outpatient Surgery, How to Perform a Proper Hand Scrub, 2009** https://www.aorn.org/outpatient-surgery/article/2009-May-how-to-perform-a-proper-hand-scrub	
SUB-SECTION C: Instrument Processing				
7-C-1	The facility has a written protocol for the reprocessing of all instruments and disinfection of all equipment used in patient care consistent with the manufacturer's instructions for use.	A B C	**Interpretive Guidance:** The intent is to minimize the risk of cross-contamination and infection. A written policy and procedure are necessary to ensure that the reprocessing of instruments and disinfection of all equipment used in patient care occurs consistently and is in accordance with the manufacturer's instructions for use.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Instrument and equipment processing may be performed off-site by an outside vendor under contract. When this service is performed through a contracted provider, it must be part of the facility's written quality improvement program. **Evaluating Compliance:** • Review the written policies and procedures for reprocessing all instruments and equipment used in patient care. • Interview staff regarding their knowledge of these policies and procedures. • Are all reusable medical equipment and point-of-care devices (e.g., blood glucose meters and other point-of-care devices, blood pressure cuffs, oximeter probes, surgical instruments, endoscopes) cleaned and reprocessed (disinfected or sterilized) prior to use on another patient or when soiled in accordance with manufacturer's instructions for use? • As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			surveyors; however, it is **not** a required form for all facility types. • Is there a separation between clean and soiled equipment maintained to prevent cross-contamination? • Are the manufacturer's instructions for reprocessing consulted and adhered to? • Are the manufacturer's instructions for reprocessing reusable medical equipment and disinfecting patient equipment readily available and used to establish clear operating procedures and training content for the facility? Are instructions posted at the site where equipment reprocessing is performed? • Do reprocessing personnel have training in the reprocessing steps and the correct use of PPE necessary for the task? • Do personnel responsible for disinfecting patient care equipment have training? • Are the training and competencies of the personnel responsible for reprocessing and/or disinfection of patient equipment documented initially upon assignment of their duties, whenever new equipment is introduced, and periodically (e.g., annually)? • If the reprocessing of instruments is performed through a contracted service, has this service been added to the facility's written quality improvement program? • Interview staff and review the written contract. • How does the facility ensure that the outside vendor meets all applicable QUAD A	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			standards? Is a process in place to validate compliance, staff competence, quality, etc? Are these processes outlined in a written contract between the facility and the outside vendor? **ANSI/AAMI ST79: 2017 & 2020 Amendments; Comprehensive guide to steam sterilization and sterility assurance in health care facilities** https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188 **CDC Recommendations for Disinfection and Sterilization in Healthcare Facilities, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html **CDC Disinfection and Sterilization Guideline, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html **CDC Disinfection of Healthcare Equipment, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html **AORN Guideline Implementation: Surgical Instrument Cleaning, 2015** https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2015.03.005 **AORN Back to Basics: Instrument Cleaning, 2017** https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2017.01.001	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AORN Surgical Instrument Decontamination: A Multistep Process, 2019 https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.12784	
7-C-2	There is strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.	A B C	**Interpretive Guidance:** The intent is to minimize cross-contamination of surgical equipment. The workflow moves from clean to dirty. **Evaluating Compliance:** • Interview staff. • Is there a strict segregation between clean and soiled equipment maintained to prevent cross-contamination? • Is the workflow from clean to dirty? • Observe practice. **ANSI/AAMI ST79:2017 & 2020 Amendments; Comprehensive guide to steam sterilization and sterility assurance in health care facilities** https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-C-3	The instrument preparation and assembly area (clean processing area) are separated by walls or space from the instrument cleaning and decontamination area (reprocessing area).	A B C	**Interpretive Guidance:** The intent is to prevent cross-contamination and healthcare-associated d infections. There is a designated dirty area and a designated clean area. The workflow moves from clean to dirty to minimize cross-contamination. A unidirectional dirty-to-clean workflow allows items to move progressively from being contaminated to being safe to handle with an area in between to reduce the risk of contamination. AAMI "Functional Workflow Patterns" states: In ambulatory surgery and office-based surgical facilities where separate rooms might not be possible, the decontamination sink should be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If a screen is used, it should extend a minimum of 4 feet above the sink rim. **Evaluating Compliance:** • Interview staff. • Observe staff processing instruments. Is the clean processing area separated from the instrument cleaning area?	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-C-4	Single-use devices are not reprocessed unless they are approved by the FDA for reprocessing. Reprocessing of these devices is done by an FDA-approved reprocessor.	A B C	**Interpretive Guidance:** The intent is to decrease the risk of cross-contamination and infections. Safe reprocessing of single-use devices requires the following: • FDA approval for re-use of single-use devices • Re-processing occurs in accordance with the manufacturer's instructions • These devices are intended for a limited number of additional uses after initial use and only after adequate cleaning, disinfecting, and re-sterilization by validated techniques as specified by the manufacturer • The manufacturer will not guarantee the integrity of the product once the designated number of re-sterilizations has been achieved. **Evaluating Compliance:** • Is the reprocessing of single use devices consistent with the manufacturer's IFUs? • Interview staff. • Review the facility's documentation of the processing of single use devices. Does the facility document the reprocessing details of each single-use device to enable product identification, device traceability, and number of sterilizations the device has undergone to ensure that the manufacturer's instructions are not exceeded? • Generally:	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			➢ Reusable gel or silicone breast implant sizers can be re-sterilized ten (10) additional times after initial use. Saline breast sizers may **not** be reprocessed. ➢ Reusable laryngeal mask airways can be used up to forty (40) times **FDA Reprocessing Single-Use Medical Devices: Information for Health Care Facilities** https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-single-use-medical-devices-information-health-care-facilities **CDC Reuse of Single-Use Devices, 2008** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/reuse-single-use-devices.html	
SUB-SECTION D: Sterilization				
7-D-1	All instruments used in patient care are sterilized, where applicable.	A B C	**Interpretive Guidance:** The intent is to minimize cross-contamination and infection. Critical equipment (e.g., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments) must be sterilized. Laryngoscope blades and laryngeal mask airways (LMAs) are considered semi-critical equipment.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Review sterilization policies and procedures. • Interview staff. • If the facility does not have a sterilizer, how is instrument processing performed? How is it documented? • As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. • Is there documentation that the sterilizer(s) achieved the time and temperature required for sterilization (either printout or manual documentation of time and temperature) required in the manufacturer's instructions for use? (Documentation of settings does not qualify for compliance – need actual documentation that each load achieved the time and temperature set for sterilization). All sterilization parameters should be set according to those validated by the manufacturer. Some complex instruments or lumened instruments have extended sterilization times and the pre-sets on the sterilizers would not meet the requirements.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review personnel files of staff responsible for decontamination and processing surgical instruments to determine training and competency validation. • Observe practice. **AAO Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments - 2018** https://www.aao.org/education/clinical-statement/guidelines-cleaning-sterilization-intraocular **ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities** https://array.aami.org/doi/book/10.2345/9781570208027 **CDC Sterilization Practices** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **CDC Recommendations for Disinfection and Sterilization Guidelines in Healthcare Facilities, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html#tocBox	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-D-2	The facility has at least one autoclave which uses high pressure steam and heat, or all sterile items are single-use disposable, or the facility has contracted with an outside vendor to process instruments. If soiled instruments are processed immediately for sterilization, they are to be treated with an enzymatic cleaner per the manufacturer's instructions for use.	A B C	**Interpretive Guidance:** The intent is to ensure the proper sterilization of all instruments and minimize infections. Instrument and equipment processing may be performed off-site by an outside vendor under contract. When this service is performed through a contracted provider, it must be part of the facility's written quality improvement program. **Intraocular Surgical Instruments** must be cleaned and sterilized in strict accordance with the manufacturer's instructions for use and nationally accepted standards of practice. Toxic anterior segment syndrome (TASS) is an acute severe inflammatory reaction to a toxic contaminant introduced into the anterior chamber during intraocular surgery. Cleaning and decontamination, which include thorough rinsing and flushing, should precede disinfection or sterilization. It is recommended that ophthalmic instrumentation should be cleaned separately from nonophthalmic surgical instruments. Contaminated and soiled instruments should also be cleaned in an area separate from where packaging and sterilization take place. **Evaluating Compliance:** • As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. • The processing of instruments and equipment may be performed off-site by an outside vendor under contract. Interview staff and review the written contract. • How does the facility ensure that the outside vendor meets all applicable QUAD A standards? Is a process in place to validate compliance, staff competence, etc.? Are these processes outlined in a written contract between the facility and the outside vendor? • If the reprocessing of instruments is performed through a contracted service, has this service been added to the facility's written quality improvement program? • Observe practice, if possible. **ANSI/AAMI ST79:2017 & 2020 Amendments; Comprehensive guide to steam sterilization and sterility assurance in health care facilities** https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AAO Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments - 2018 https://www.aao.org/education/clinical-statement/guidelines-cleaning-sterilization-intraocular **Toxic anterior segment syndrome (TASS): A review and update, 2023** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10841787/ **WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities**https://iris.who.int/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1	
7-D-3	Additional methods in use can be chemical autoclave (Chemclave©) or gas (ethylene oxide/EO) sterilizer.	A B C	**Interpretive Guidance:** The intent is to ensure the safe use of chemical sterilizers and minimize infections. Chemical sterilizers are the least common form of sterilization, due to their cost and potential hazards if handled incorrectly. However, when used properly, chemical sterilizers offer the benefits of both steam sterilizers and dry heat sterilizers – resulting in the reduced wear of metal instruments while requiring a shorter sterilization time. Chemical sterilizers use either Ethylene Oxide (EtO), or a combination of alcohol, formaldehyde, ketone, acetone, and water to create a chemical vapor for sterilization. Like	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			steam sterilizers, they also rely on a combination of high temperature, high pressure, and time. **Evaluating Compliance:** • Interview staff regarding training and competency validation. • Review personnel files to confirm training and competency validation. • Are policies and procedures consistent with the manufacturer's instructions for use? Are necessary precautions taken to limit staff exposure to hazardous gases? • Observe practice, if possible. **CDC Ethylene Oxide "Gas" Sterilization** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/ethylene-oxide-sterilization.html **CDC Peracetic Acid Sterilization** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/peracetic-acid-sterilization.html	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-D-4	Gas sterilizers and automated endoscope re-processors (AER) must be vented and tested for occupational exposure in accordance with the manufacturer's specifications.	A B C	**Interpretive Guidance:** The intent is to ensure the safe use of gas sterilizers and AERs. **Evaluating Compliance:** • Is practice based on the manufacturer's IFU. Is the recommended safety testing conducted? • Are essential steps for endoscope processing addressed? • Interview staff regarding the use of the equipment and the safety training administered by the facility. • Review reports to determine whether the facility regularly tests for occupational exposure and addresses any problems with corrective action. • Observe practice, if possible.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
7-D-5	The facility must monitor each autoclave load for the appropriate mechanical indicators (e.g., time, temperature, and pressure). Chemical indicators (external and internal) must be used according to the sterilizer manufacturer's instructions. The use of a type 1 and type 5 indicator is required. Minimally, a biological indicator (spore test) is used weekly for each sterilizer. A biological indicator is required for every load containing implantable items. Evidence of sterilization assurance monitoring is recorded for every load and any corrective action is documented.	A B C	**Interpretive Guidance:** The intent is to minimize infections. Sterilization must be performed in accordance with the manufacturer's instructions for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments). Sterilizer equipment is monitored and tracked for sterility and proper functioning. This is generally done in the sterilization log. **Physical/Mechanical Indicators (Monitors)**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Physical/mechanical monitors (embedded in the sterilization equipment) register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence that the sterilization system has met the set parameters (or has not, and corrective action is needed). **Chemical Indicators** Chemical indicators (as recommended by the manufacturer) should be placed on the outside and inside of each sterilized package unless the internal indicator is readable through the packaging material. Chemical indicators are grouped into 6 types based on how they work. Type 1 and Type 5 indicators are the most currently used. **External Chemical Indicators** · Type 1 Process Indicators are tapes or labels that change colors to show that the package has been exposed to the sterilization process. They should be applied to the outside of every package unless an internal indicator is visible. · Type 2 are Indicators for Specific Tests to detect air leaks, ineffective air removal, and the presence of non-condensable gases. Also known as the Bowie-Dick test, it is intended for daily use in dynamic-air-removal (pre-vac) sterilizers. They should be run through a cycle in an empty chamber before the first load of the day to test the system.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Internal Chemical Indicators • Type 3 are designed to react to a single parameter (e.g., sterilization time, temperature, or pressure). • Type 4 are designed to react to multiple parameters of the sterilization process. • Type 5* are Integrating Indicators, that react to all critical parameters over a specified range of sterilization cycles. These indicators include a spore strip, in which changing color signals the cycle's ability to eliminate microbes. For use inside individual packs, peel pouches, and rigid containers. • Type 6** are Emulating Indicators, that react to a specific sterilization cycle and will show a small deviation in any of the critical parameters (sterilization time, temperature, or pressure). *Class 5 Chemical Integrators react to the three critical variables of a steam sterilization cycle (time, temperature, and the presence of steam) of which the performance is required to correlate to a biological indicator (BI). As a result, Class 5 integrator results are like those of a BI and can detect failures where the selected temperature isn't reached. This failure condition is likely to occur when there is incorrect packaging and loading,	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			air/steam mixtures, and/or incorrect cycle for load contents. **Risk: Class 6 Chemical Indicators (CI) react to the three critical variables for a specified cycle type, and their performance may or may not correlate to a Biological Indicator. It is important to realize that if you run multiple exposure times and temperatures, you must use a distinct Class 6 CI to monitor each cycle time and temperature. Because Class 6 CIs are not required to correlate to a BI, a Class 6 indicator could reveal a pass where a BI would indicate a failure. **Evaluating Compliance:** • Review the facility policies and procedures. • Review the sterilization documentation. • Interview staff. • Observe practice if possible. • As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may help identify the types of observations surveyors should make in all facility types. This form may also help; however, it is **not** a required form for all facility types.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC Recommendations for Disinfection and Sterilization Guidelines in Healthcare Facilities, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html#tocBox **CDC Sterilization Practices, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **Halyard Health Sterilization Pouches: What You Need to Know About the Essential Medical Sterilization Product, 2023** https://www.halyardhealth.com/articles/sterilization/sterilization-pouches-what-you-need-to-know **WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities** https://iris.who.int/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-D-6	Sterile instruments and supplies are packaged according to the manufacturer's instructions for use (IFU) and sealed effectively. Self-sealing peel pouches must be folded on the crease and may only be double-pouched when the process is validated by the manufacturer.	A B C	**Interpretive Guidance:** The intent is to ensure the safe packaging of sterile instruments and supplies and minimize infections. **Evaluating Compliance:** • Is packaging consistent with the manufacturer's IFUs? • Interview staff. • Observe peel pouches for the following: ➢ Overfilled with instruments ➢ Instruments in the closed position ➢ Sealed effectively to ensure that the instruments remain sterile ➢ Only double-pouched if validated for such, inner pouch is not folded • Minimally, is the following information on the label of sterile supplies? ➢ Sterilizer used ➢ Cycle or load number ➢ Date of sterilization As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CDC Sterilization Practices, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **Understanding the Parts and Functions of Surgical Instruments for Sterile Processing, 2024** https://sterileprocessingtech.org/understanding-the-parts-and-functions-of-surgical-instruments-for-sterile-processing/ **WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities** https://iris.who.int/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1	
7-D-7	Each sterilized pack is labeled with the date of sterilization and, when applicable, with the expiration date. When the facility has more than one sterilizer, labels must also identify the sterilizer used.	A B C	**Interpretive Guidance:** The intent is to ensure the safe labeling of sterilized packs and minimize infections. Adequate information on the package's label assists the facility in monitoring supplies that have time-related expiration dates and to track and recall instruments associated with a sterilization failure. **Evaluating Compliance:** • Minimally, is the following information on the label of sterile supplies? ➢ Sterilizer used ➢ Cycle or load number	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			➢ Date of sterilization ➢ Expiration date, if applicable ➢ Initials of the processor As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist surveyors in identifying the types of observations they should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. **CDC Sterilization Practices, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities** https://iris.who.int/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-D-9	Comprehensive monitoring records that include quality control are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.	A B C	**Interpretive Guidance:** The intent is to ensure that the sterilizer is not contaminated and minimize infections. **Evaluating Compliance:** • Review sterilization or other disinfection process logs. Logs may be hard copy or electronic. • For each sterilization cycle, are the following elements documented? ➢ Type of sterilizer and cycle used ➢ Load identification number ➢ Load contents ➢ Exposure parameters (e.g., time and temperature) ➢ Operator's name or initials ➢ Results of mechanical, chemical, and biological monitoring. ➢ Number of re-sterilizations if applicable **CDC Sterilization Practices, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **CDC Best Practices for Sterilization Monitoring in Dental Settings, 2024** www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-D-10	There is a written policy and procedure for the management of a positive biological indicator.	A B C	**Interpretive Guidance:** The intent is to ensure that positive biological indicators are managed consistent with the manufacturer's IFUs and minimize infections. **Evaluating Compliance:** • Review the policies and procedures for the management of a positive biological indicator. • Interview staff. • Can instruments used within the time frame of the positive test be tracked? **CDC Sterilization Practices, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html **CDC Best Practices for Sterilization Monitoring in Dental Settings, 2024** www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
7-D-11	Immediate use steam sterilization (IUSS) is not done on a routine or frequent practice.	A B C	**Interpretive Guidance:** The intent is to minimize infections. IUSS, formerly known as "flash sterilization, is defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one (1) case to another. The use of IUSS should be minimized. Situations when IUSS may be appropriate include:	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• When a specific instrument is needed for an emergency procedure. • When a non-replaceable instrument has been contaminated and needs to be replaced in the sterile field immediately. • When an item has dropped on the floor and is needed to continue a surgical procedure. **IUSS is NOT acceptable in the following situations:** • When used to compensate for inadequate inventory of surgical instrument sets • When a loaner tray was not brought to the facility in time for routine reprocessing • For implant devices, except in a documented emergency situation when no other option is available. • For post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or other prion-associated diseases. • On devices or loads that have not been validated with the specific cycle used; or • On devices that are sold by the manufacturer already processed and packaged as sterile and intended for single use only **Evaluating Compliance:** As a resource, see Part 2, Section III, Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			(https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. • Review the immediate use steam sterilization log to determine if IUSS is performed frequently and/or if more instruments should have been purchased for use. • Observe practice, if possible. **ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities** https://array.aami.org/doi/book/10.2345/9781570208027 **APIC Immediate-Use Steam Sterilization** https://www.apic.org/Resource_/TinyMceFileManager/Position_Statements/Immediate_Use_Steam_Sterilization_022011.pdf **CDC Flash Sterilization** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/flash-sterilization.html	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: High-Level Disinfection (HLD)				
7-E-1	High-level disinfection is performed upon heat-sensitive endoscopic equipment and other medical devices classified as semi-critical, but only when recommended by the manufacturer's instructions for use (IFU).	A B C	**Interpretive Guidance:** The intent is to minimize infection. High-level disinfection is performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes, such as reusable flexible endoscopes, and some laryngoscope blades). Rigid scopes and some laryngoscopes are approved for steam sterilization so the manufacturer's IFU should always be referenced. **Evaluating Compliance:** • Interview staff. • As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. **CDC Disinfection of Healthcare Equipment, 2023**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html **WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities** https://iris.who.int/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1	
7-E-2	Endoscopes are processed in accordance with a written policy and procedure in accordance with recognized guidelines and standards of practice. The policy must address how scopes are treated at the point of use, transported, cleaned, high-level disinfected, and stored.	A B C	**Interpretive Guidance:** The intent is to minimize infection. Facilities must process flexible endoscopes according to recognized national guidelines that address treatment at the point of care, transportation, cleaning, high-level disinfection, and storage. The use of AERs can enhance the efficiency, consistency, and reliability of endoscope reprocessing by automating and standardizing several important reprocessing steps, thereby reducing the possibility of human error. The use of AERs reduces the exposure of reprocessing personnel to harmful chemical germicides and may lessen health problems attributed to the reprocessing of endoscopes. The use of AERs for endoscope reprocessing is strongly recommended by the American Society of Gastrointestinal Endoscopy.The facility should	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			define “delayed processing” and determine what additional procedures should be performed when processing is delayed. • **Treating at the Point of Use** Pre-clean flexible endoscopes and reusable accessories by following the device manufacturer’s instructions for use (IFU). Pre-cleaning is performed immediately following completion (in the procedure room) of the endoscope procedure to help prevent the formation of biofilm. • **Leak-Testing:** For endoscopes that require leak testing, the leak testing is performed using the manufacturer’s IFU after each use and prior to manual cleaning. Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope. • **Manual Cleaning:** Perform meticulous manual cleaning, including brushing and flushing channels and ports consistent with the manufacturer’s IFU before performing high-level disinfection (HLD) or sterilization. Perform manual cleaning within the timeframe specified in the manufacturer’s IFU. Manual cleaning is the most critical step in the disinfection process since residual organic material can reduce the effectiveness of HLD and sterilization. • **Visual Inspection:** After manual cleaning, visually inspect the endoscope and its	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			accessories. Visual inspection provides additional assurance that the endoscope and its accessories are clean and free of defects. Complex devices such as flexible endoscopes may require the use of lighted magnification or additional methods to assist with the inspection process. • **Disinfection or Sterilization:** Following cleaning and visual inspection, perform HLD or sterilization in accordance with the manufacturer's IFU. Carefully review and adhere to the endoscope manufacturer's reprocessing instructions and to the IFU for chemicals or sterilants and any equipment (e.g., automated endoscope reprocessors) used for reprocessing to help ensure that effective disinfection occurs. • **Storage:** After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage, and promotes drying. Store processed flexible endoscopes in a cabinet that is either of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet OR **or** designed and intended by the manufacturer for horizontal storage of flexible endoscopes. Scopes should not be stored within three (3) feet of a sink.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• **Documentation:** Maintain documentation of adherence to these essential steps each time an endoscope is reprocessed. Documentation is essential for quality assurance purposes and for patient tracing in the event a look back is necessary. **Evaluating Compliance:** • Review endoscope processing protocols. Ensure delayed processing is defined and that additional procedures are addressed when processing is delayed. • Interview staff. • Observe the processing of endoscopes, if possible. • Are the following essential steps addressed? Are these steps followed in practice? • Review the facility policies and procedures. Are they based on the manufacturer's IFU to determine the recommended safety testing and how often the testing should be performed? Are essential steps for endoscope processing addressed? • Interview staff regarding the use of the equipment and the safety training administered by the facility. • Review reports to determine whether the facility regularly tests for occupational exposure and addresses any problems with corrective action. • Observe practice, if possible.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the facility policies and procedures. Are they based on the manufacturer's IFU to determine the recommended safety testing and how often the testing should be performed? Are essential steps for endoscope processing addressed? • Interview staff regarding the use of the equipment and the safety training administered by the facility. • Review reports to determine whether the facility regularly tests for occupational exposure and addresses any problems with corrective action. • Review personnel files to confirm training and competency validation. • Observe practice, if possible. **Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC), 2015** https://www.cdc.gov/hicpac/media/pdfs/essential-elements-508.pdf **CDC Disinfection and Sterilization – Summary, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.htm	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION F: Cleaning				
7-F-1	The entire operating room suite is cleaned and disinfected according to an established schedule that is adequate to prevent cross-contamination.	A B C	**Interpretive Guidance:** The intent is to ensure that the cleaning and disinfection of the entire operating room suite is adequate to prevent cross-contamination. **Evaluating Compliance:** • Interview staff. • Review documentation of cleaning. • Review the disinfectant used for cleaning, Is it intermediate-level, a medical grade, and EPA-registered? • As a resource, see Part 2, Section IV. Environmental Infection Control, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. **AORN Guidelines in Practice: Environmental Cleaning, 2021** https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.13376	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-F-2	The facility's policies and procedures address cleaning of the operating room suite, including the: - Cleaning schedule - Process for cleaning between cases - Process for terminal cleaning after the last case of the day - Use of intermediate-level, medical-grade disinfectants EPA-registered as virucidal, bactericidal, tuberculocidal, and fungicidal.	A B C	**Interpretive Guidance:** The intent is to ensure that the cleaning and disinfection of the entire operating room suite is adequate to prevent cross-contamination. **Evaluating Compliance:** • Interview staff and review policies and procedures for cleaning and disinfecting the entire operating suite. • Review documentation of cleaning. • Review the disinfectant used for cleaning, Is it intermediate-level, a medical grade, and EPA-registered? • As a resource, see Part 2, Section IV. Environmental Infection Control, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is **not** a required form for all facility types. **AORN Guidelines in Practice: Environmental Cleaning, 2021** https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.13376	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-F-3	There is a written policy for cleaning spills, especially spills that may contain blood borne pathogens.	A B C	**Interpretive Guidance:** The intent is to ensure safeguards to protect workers against health hazards related to bloodborne pathogens. **Evaluating Compliance:** • Determine whether the facility has a procedure for decontamination after gross spills of blood or other bodily fluids. • Interview staff. **OSHA Bloodborne Pathogens and Needlestick Prevention** https://www.osha.gov/bloodborne-pathogens/standards	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
7-F-4	All blood and body fluid spills are cleaned using medical-grade germicides that are virucidal, bactericidal, tuberculocidal, and fungicidal. A spill kit is available and readily accessible.	A B C	**Interpretive Guidance:** The intent is to ensure safeguards are in place to protect workers against health hazards related to blood and body spills. **Evaluating Compliance:** • Interview staff and review the policy and procedure specifying the method to clean up blood and body spills. • What type of germicides are used? Are the germicides medical grade? Are they viricidal, bactericidal, tuberculocidal, and fungicidal? Are they EPA-registered? If a spill occurs, observe the clean-up process. • Is a spill kit available and clearly labeled?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Is the spill kit accessible and located where spills are most likely to occur? • Do staff know where the spill kit is located? • Does the spill kit contain sufficient absorbent materials? • Does the spill kit include the necessary PPE? • Does the spill kit contain tools to contain and clean up spilled blood and body fluids? • Does the spill kit include instructions for proper disposal of used absorbent materials and contaminated waste? **OSHA Worker Protections Against Occupational Exposure to Infectious Diseases** https://www.osha.gov/bloodborne-pathogens/worker-protections **The Complete Guide to OSHA Spill Kit Regulations, 2024** https://www.homecoreinspections.com/resources/osha-spill-kit-regulations	
7-F-5	Facility policies and procedures have been developed for use by housekeeping personnel for cleaning floors, tables, walls, ceilings, counters, furniture, and fixtures of the operating suite.	A B C	**Interpretive Guidance:** The intent is to ensure that housekeeping staff are consistently and effectively cleaning the facility to minimize infection. Housekeeping services may be performed by an outside vendor under contract. When this service is performed through a contracted service, the service must be part of the facility's written quality	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			improvement program and must have what areas are cleaned specific to the facility. **Evaluating Compliance:** • Review written policies and procedures. • Interview staff. • Review the documentation of cleaning. Is cleaning done consistent with the facility's policies and procedures? • How does the facility ensure that the outside vendor meets all applicable QUAD A standards? Is a process in place to validate compliance, staff competence, etc.? Are these processes outlined in a written contract between the facility and the outside vendor? • If the housekeeping services are performed through a contracted service, has this service been added to the facility's written quality improvement program? **CDC Environmental Cleaning Procedures, 2024** https://www.cdc.gov/healthcare-associated-infections/hcp/cleaning-global/procedures.html	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
7-F-6	Instrument handling and reprocessing areas are cleaned and maintained.	A B C	**Interpretive Guidance:** The intent is to ensure that instrument handling and reprocessing areas are cleaned and maintained to minimize infection. **Evaluating Compliance:** • Interview staff. • Inspect instrument handling and reprocessing areas for cleanliness. • Review cleaning logs. Is cleaning done as specified in the facility's policies and procedures? **CDC Cleaning, 2023** https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/cleaning.html **CDC Disinfection and Sterilization Guidelines** https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 8: CLINICAL RECORDS

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: General Clinical Records				
8-A-1	The facility must maintain separate, complete, comprehensive and accurate clinical records to ensure adequate patient care.	416.47 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-A-2	The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.	416.52 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-A-3	The facility must develop and maintain a system for the proper collection, storage, and use of clinical records.	416.47(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-A-4	Clinical records must be kept secure and confidential, consistent with HIPAA regulations.	A B C	**Interpretive Guidance:** The intent is to ensure that the facility takes measures to protect both hard copy and electronic health information to ensure confidentiality, integrity, and security in accordance with current HIPAA regulations. All clinical records are secure and confidential to prevent unauthorized access, intentional damage, or theft in accordance with Federal, State, and local laws. Electronic Clinical records (EMRs) must have controlled access, such as passwords or PINs. Access to patient information is limited to authorized individuals, such as patients' doctors or nurses. **Evaluating Compliance:** • Interview staff. • Are clinical records readily accessible to authorized personnel? • Are clinical records properly stored in secure locations where they are protected from fire, water damage, and other threats? The clinical record system must ensure that	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			clinical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. • Does the facility ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records? Patient records must be secure at all times. • Does the facility have sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy, or duly authorized as having a need to know? Are EMRs password-protected?	
8-A-6	Electronic health records (EHR) must comply with security and privacy obligations under current HIPAA regulations.	A B C	**Interpretive Guidance:** The intent is to ensure that the facility takes measures to protect electronic health information to ensure confidentiality, integrity, and security in accordance with current HIPPA regulations. **Evaluating Compliance:** • Does the EHR comply with current HIPPA regulations? • Is the EHR password protected?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-A-7	The ASC must maintain a clinical record for each patient. Every record must be accurate, legible, and promptly completed.	416.47(b) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-A-9	Clinical records must be retained the number of years as required by state and/or federal law; or a minimum of three (3) years to comply with the QUAD A three-year survey cycle.	A B C	**Interpretive Guidance:** The intent is to ensure clinical records are retained for a minimum of three (3) years. Clinical records may be in an electronic or paper-based format or a combination of both. **Evaluating Compliance:** • Interview staff. • Are clinical records retained for the number of years required by QUAD A, and state law? The more stringent requirement applies. • What is the process for destroying paper-based records? Who is authorized to destroy clinical records? • Are paper-based records destroyed after conversion to an EMR within a reasonable timeframe? Once the data conversion is successfully completed, it is safe to destroy all paper-based information.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-A-10	Clinical records are maintained and easily accessible by the accredited facility.	A B C	**Interpretive Guidance:** The intent is to ensure that clinical records are maintained and easily accessible. Clinical records may be in an electronic or paper-based format. **Evaluating Compliance:** • Are clinical records maintained and easily accessible?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Pre-Operative Documentation				
8-B-1	Clinical records must contain patient identification.	416.47(b)(1) Standard A B C	**Interpretive Guidance:** The intent is to validate the patient's identity. The patient's identity must be clear through the use of identifiers such as name, date of birth, social security number, etc. The use of photo identification alone is not acceptable. **Evaluating Compliance:** • Review the facility policy and procedure. • Interview staff. • Review clinical records. Is the identity of the patient clear through the use of identifiers such as name, date of birth, social security number, etc. **CMS standards Interpretive Guidance can be found at:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			SOM (cms.gov) Appendix L	
8-B-2	A pre-operative surgical safety checklist must be used for each patient and noted in the patient record.	A B C	**Interpretive Guidance:** The intent is to ensure that steps to promote safe surgery are accomplished in a systematic and timely fashion through the use of a pre-operative safety checklist. **Before induction of anesthesia (with at least a nurse and anesthesia professional:** • Has the patient confirmed his/her identity, site, procedure, and consent? • Is the site marked? • Is the anesthesia machine and medication check complete? • Is the pulse oximeter on the patient and functioning? • Does the patient have a: ➢ Known allergy? ➢ Difficult airway or aspiration risk? If yes, equipment/assistance is available. ➢ Risk of greater than 500 ml blood loss (7ml/kg in children)? **Before skin incision (with nurse, anesthesia professional, and surgeon/proceduralist):** • Confirm all team members have introduced themselves by name and role.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Confirm the patient's name, procedure, and where the incision will be made. • Has antibiotic prophylaxis been given within the last 60 minutes? • Anticipated Critical Events ➢ To Surgeon: What are the critical or non-routine steps? How long will the case take? What is the anticipated blood loss? ➢ To Anesthesia Professional: Are there patient-specific concerns? ➢ To Nursing Team: Has sterility (including indicator results) been confirmed? Are there equipment issues or any concerns? • Is essential imaging displayed? **Before the patient leaves the operating room Nurse Verbally Confirms:** ➢ The name of the procedure ➢ Completion of instrument, sponge, and needle counts ➢ Specimen labeling (read specimen labels aloud, including patient name) ➢ To Surgeon, Anesthetist, and Nurse? What are the key concerns for the recovery and management of this patient? **Evaluating Compliance:** • Interview staff.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review clinical record. Are all of the elements of the WHO Surgical Safety Checklist included? **Implementation Manual: WHO Surgical Safety Checklist 2009** https://iris.who.int/bitstream/handle/10665/44186/9789241598590_eng.pdf?sequence=1	
8-B-3	The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must: - Include the time frame for medical history and physical examination to be completed prior to surgery. - Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level. - Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.	416.52(a)(1) Standard 416.52(a)(1)(i) Standard 416.52(a)(1)(ii) Standard 416.52(a)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-6	The pre-operative clinical record includes medical clearance, if based on the patient's medical history and/or procedure to be performed, it is required by the facility policy.	A B C	**Interpretive Guidance:** The intent is to ensure the patient is a candidate for the procedure in the outpatient setting. Medical clearance is required based on the patient's medical assessment in accordance with the facility's medical staff criteria and requirements. **Evaluating Compliance:** • Review the facility's policies and procedures regarding medical clearance. Is it based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws? • Interview staff. • Determine through a sample of clinical record reviews whether the facility follows its own policy.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-7	The pre-operative clinical record includes significant medical history and a physical examination covering the organs and systems commensurate with the procedure(s) are recorded on all patients and placed in the clinical record prior to the surgical procedure.	416.47(b)(2) Standard 416.52(a)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-8	Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and facility policy. The pre-surgical assessment must include documentation of any allergies to drugs and biologicals. This assessment must be placed in the patient's clinical record prior to the surgical procedure.	416.52(a)(2) Standard 416.52(a)(3) Standard 416.52(a)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-9	The patient procedural pre-operative assessment should include documentation regarding special needs such as physical impairments, disabilities, religious and/or ethnic concerns.	A B C	**Interpretive Guidance:** The intent is to ensure that the patient's special needs, if present, are assessed and documented prior to the procedure. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-10	The pre-operative clinical record includes documentation of blood pressure, pulse, respiration and temperature as taken prior to the operation.	A B C	**Interpretive Guidance:** The intent is to ensure that baseline vital signs are obtained and documented in the clinical record at the time of the patient's admission to the facility. **Evaluating Compliance:** • Interview staff. • Review the facility's policy and procedure regarding pre-operative assessments. Does it include obtaining baseline blood pressure, pulse, respiration and temperature as taken prior to the operation. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-11	The pre-operative clinical record includes documentation of all pre-operative medications given to a patient. This record includes the patient name, date, time, dose, and route of administration.	A B C	**Interpretive Guidance:** The intent is to ensure that all pre-operative medications are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-12	The pre-operative clinical record includes documentation of all intravenous fluids given pre-operatively.	B C	**Interpretive Guidance:** The intent is to ensure that all pre-operative intravenous fluids are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-13	The pre-operative clinical record includes documentation of any allergies and abnormal drug reactions.	416.47(b)(5) Standard 416.52(a)(3) Standard A B C	**Interpretive Guidance:** The intent is to ensure that all allergies to medications and their response are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-14	The pre-operative clinical record includes documentation of current medications.	A B C	**Interpretive Guidance:** The intent is to ensure that all current patient medications are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-15	The pre-operative clinical record includes documentation of medical history.	A B C	**Interpretive Guidance:** The intent is to ensure ŧ the patient's medical history is documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-17	The pre-operative clinical record includes documentation of any previous operations.	A B C	**Interpretive Guidance:** The intent is to ensure that the patient's previous operations are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-18	The pre-operative clinical record includes documentation of perioperative bleeding risk, including medical conditions and anticoagulant medication taken up to the day of the operation.	A B C	**Interpretive Guidance:** The intent is to ensure that any perioperative patient bleeding risk(s) are documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-19	A written pregnancy testing policy must be in place that requires a discussion and documentation of the issue with each patient, as appropriate.	A B C	**Interpretive Guidance:** The intent is to ensure that the patient's pregnancy status is discussed and documented in the clinical record, as appropriate. A CLIA certificate is required to perform point-of-care testing. See section 3-H. **Evaluating Compliance:** • Review the facility's policies and procedures. Does it require discussion and documentation of the issue with each patient, as applicable? • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-20	The pre-operative clinical record includes evidence that treating physicians or consultants are contacted in cases when warranted by the history and physical examination.	A B C	**Interpretive Guidance:** The intent is to ensure that treating physicians or consultants are contacted when warranted by the pre-operative history and physical and documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-21	The pre-operative clinical record includes documentation of appropriate laboratory procedures performed where indicated.	A B C	**Interpretive Guidance:** The intent is to ensure that appropriate laboratory procedures performed pre-operatively are documented in the clinical record. The facility must identify the appropriate laboratory procedures that are to be performed pre-operatively. **Evaluating Compliance:** • How does the facility define appropriate laboratory procedures? • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-22	The pre-operative clinical record includes pre-operative diagnostic studies and laboratory procedures (entered before surgery), if performed.	416.47(b)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-B-23	For patients receiving general anesthesia, surgical procedures scheduled for 60 minutes or longer, and for patients with a history of venous thromboembolism (VTE), the pre-operative clinical record includes a written screening protocol for VTE risk. This protocol and assessment tool are to be placed in the facility manual for reference.	B C	**Interpretive Guidance:** The intent is to ensure that the patient's VTE risk is identified when patients receive general anesthesia, surgical procedures scheduled for 60 minutes or more, and patients with a history of VTE. The goal is to minimize VTEs from occurring with the surgical procedure.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Venous thromboembolism (VTE), including pulmonary embolism (PE) and deep vein thrombosis (DVT), is one of the leading causes of preventable cardiovascular disease in the United States (US) and is the number one preventable cause of death following a surgical procedure. Post-operative VTE is associated with multiple short and long-term complications. The Caprini VTE risk assessment is the most extensively used and validated method for predicting postoperative VTE. However, it is not required; the facility is free to use a comparable VTE risk assessment. The facility must develop a standardized set of guidelines designed to identify patients at risk of developing VTE and determine the most appropriate preventative measures to minimize that risk based on the patient's assessed risk. The policies and procedures, protocols, and assessment tools are based on the types of procedures performed and the patient population served. **Evaluating Compliance:** • Review facility policies, procedures, and assessment tools. • Interview staff.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review clinical records for documentation of the presence of VTE risk assessment when applicable. For patients with a high-risk score (5 or greater or as defined by the facility based on the types of procedures performed and the population served), are interventions (as required by facility policies and procedures) documented? **Completion of the Updated Caprini Risk Assessment Model** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6714938/ **Caprini Risk Assessment Model for Venous thromboembolism, Recommended Intervention for Thromboprophylaxis Based on Risk of VTE.** https://thrombosiscanada.ca/wp-content/uploads/2017/04/VTE-Risk-Assessment-Tool-Caprini-Score-Card-Eng-30Apr2018.pdf	
8-B-24	The surgeon/proceduralist and the licensed or qualified anesthesia professional concur on the appropriateness of the procedures performed at the facility based on the medical status of the patient, age and physiological appropriateness of the patient, and qualifications of the providers and the facility resources. This concurrence must be documented in the clinical record.	A B C	**Interpretive Guidance:** The intent is to ensure that procedures performed at the facility are appropriate based on the patient's medical status, age and physiological appropriateness, and qualifications of the providers and facility resources. The surgeon/proceduralist and anesthesia professional concur on the appropriateness of the procedures.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			If the surgeon/proceduralist also administers the anesthesia, this standard is not applicable (NA). If the RN administers sedation under the surgeon/proceduralists orders, this standard is NA. An RN is not considered a licensed or qualified anesthesia professional. The facility addresses where and how this concurrence is documented through its policies and procedures. It could be included on the pre-op checklist or time-out procedure. A check box is acceptable; a signature is not required. **Evaluating Compliance:** • Review the facility's policies and procedures. • Determine how and where the concurrence is documented. Interview staff. • Review clinical records to validate documentation.	
8-B-25	Immediately before surgery a physician must examine the patient to evaluate the risk of the procedure to be performed.	416.42(a)(1) Standard 416.42(a)(1) (i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-B-26	Immediately before surgery a physician or anesthesia professional as defined at 42 CFR 410.69(b) of this chapter must examine the patient to evaluate and document the risk of anesthesia.	416.42(a)(1) Standard 416.42(a)(1) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: Informed Consent				
8-C-1	Properly executed informed consent forms are always obtained, which authorizes the surgeon/proceduralist by name to perform surgery and describes the operative procedure.	416.47(b)(7) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-C-2	Expectations, alternatives, risks, and complications are discussed with the patient, and these are documented.	A B C	**Interpretive Guidance:** The intent is to ensure a properly executed informed patient consent for the procedure is obtained and documented. **Evaluating Compliance:** • Review the facility's policies and procedures. Are these elements addressed? • Interview staff. • Review clinical records to validate documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-C-3	The written informed consent provides consent for the administration of anesthesia or sedatives under the direction of the surgeon, anesthesiologist, or CRNA.	A B C	**Interpretive Guidance:** The intent is to ensure a properly executed informed patient consent for the administration of anesthesia or sedatives is obtained and documented. **Evaluating Compliance:** • Interview staff. • Review clinical records: • Is a properly executed informed consent for anesthesia or sedatives present? • Is the consent for anesthesia or sedatives present in the patient's clinical record prior to the procedure? • If the anesthesia consent is integrated into the surgical consent the anesthesia professional responsible for administration of anesthesia must participate in the	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			informed consent process and discussion of the planned anesthesia care.	
8-C-4	The patient signs a consent form if research protocols, videography, or photography are to take place.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: Advanced Directives				
8-D-1	The ASC must provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms.	416.50(c) Standard 416.50(c)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-D-2	The ASC must inform the patient or, as appropriate, the patient's representative or surrogate of the patient's right to make informed decisions regarding the patient's care.	416.50(c) Standard 416.50(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-D-3	The ASC must document in a prominent part of the patient's current clinical record, whether or not the individual has executed an advance directive.	416.50(c) Standard 416.50(c)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: Laboratory, Pathology, X-Ray, Consultation, Treating Physician Reports, Etc.				
8-E-1	Reports of: laboratory, pathology, X-ray, consultation, treating physician, and any other diagnostic tests are maintained in the clinical record and are accessible for review prior to the procedure.	A B C	**Interpretive Guidance:** The intent is that reports are accessible for review in the medical record prior to the procedure. Reports can be in hard copy or electronic form. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
8-E-2	All laboratory results must be reviewed and initialed by the anesthesia professional, registered nurse, or surgeon/proceduralist within one (1) week of receipt of the results. If a registered nurse reviews laboratory results and the results are abnormal, documentation must be present in the clinical record that the anesthesia professional and surgeon/proceduralist are aware of the abnormality.	A B C	**Interpretive Guidance:** The intent is to ensure that laboratory results are reviewed and that the anesthesia professional and surgeon/proceduralist review and initial any abnormal laboratory results. The facility identifies abnormal results are documented in both hard copy and/or electronic clinical records. In an electronic medical record, the reviewed results must indicate an electronic authentication that the licensed professional has reviewed the results. This includes the name and title of the licensed professional, along with the date and time the licensed healthcare professional reviewed the result or an electronic signature.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Interview staff. • If an RN reviews the laboratory results and abnormal results have been reported, is there documentation in the patient's clinical record that abnormal results have been reported to the anesthesia provider or surgeon/proceduralist? • Is there documentation that the anesthesia professional and surgeon/proceduralist reviewed abnormal results? • Review clinical records to validate documentation	
8-E-4	All other reports, such as pathology reports and medical clearance reports, must be documented as reviewed by the surgeon/proceduralist.	A B C	**Interpretive Guidance:** The intent is to ensure that the surgeon/proceduralist has reviewed all reports. The facility policies and procedures identify how and where this review is documented. in both hard copy and/or electronic clinical records. In an electronic medical record, the reviewed results must indicate an electronic authentication that the licensed professional has reviewed the results. This includes the name and title of the licensed professional, along with the date and time the licensed healthcare professional reviewed the result or an electronic signature. **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Interview staff. • Review clinical records to validate documentation.	
8-E-7	Clinical records must contain findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.	416.47(b)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-E-8	All surgical specimens must be submitted for pathological processing except those exempted by the governing body.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Review clinical records for related documentation.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
8-E-9	The name of the pathologist must be on all pathology reports.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Review clinical records for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-E-13	All surgical specimens sent out for pathology must be documented in a pathology specimen log, which minimally includes the date, patient's name, number and type of specimen (biopsy, swab, fluid, etc.), and physician's name.	A B C	**Interpretive Guidance:** The intent is to ensure that surgical specimens sent for pathology are identified and tracked. **Evaluating Compliance:** • Interview staff. • Review the pathology specimen log to validate that all required elements are included.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION F: Anesthesia Care Plan				
8-F-4	The anesthesia care plan is based on a review of the clinical record.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-F-5	The anesthesia care plan is based on medical history.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-F-6	The anesthesia care plan is based on prior anesthetic experiences.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-F-7	The anesthesia care plan is based on drug therapies.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-F-8	The anesthesia care plan is based on medical examination and assessment of any conditions that might affect the pre-operative risk.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	
8-F-9	The anesthesia care plan is based on a review of the medical tests and consultations.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-F-10	The anesthesia care plan is based on a determination of pre-operative medications needed for anesthesia.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 –	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			8F12. A notation of "See chart" in the clinical record is not acceptable. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation. .	
8-F-11	The anesthesia care plan is based on providing pre-operative instructions.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. A notation of "See chart" in the clinical record is not acceptable. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-F-12	The anesthesia care plan is based on allergy history.	A B C	**Interpretive Guidance:** The intent is to ensure the development of a safe individualized anesthesia plan for the patient. The surveyor is not expected to evaluate the practice of anesthesia or make a medical judgment about the anesthesia care plan. Instead, the surveyor is looking for evidence that the plan is based on the elements listed in standards 8F4 – 8F12. **Evaluating Compliance:** • Interview the anesthesia professionals. • Review the pre-anesthesia assessment and anesthesia care plan in the clinical record for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SUB-SECTION G: Intra-Operative Documentation

8-G-1	A “Time Out” protocol is in place, practiced, and documented in the clinical record prior to every operation. This protocol must include: A pre-operative verification process including clinical records, imaging studies, surgical fire risk, and any implants identified, and be reviewed by the operating room team. Missing information or discrepancies must be addressed in the clinical record at this time. - Marking the operative site: Surgical procedures calling for right/left distinction; multiple structures (breasts, eyes, fingers, toes, etc.) must be marked while the patient is awake and aware, if possible. The person performing the surgery should do the site marking. The site must be marked so that the mark will be visible after the patient has been prepped and draped. A procedure must be in place for patients who refuse site marking. - Immediately before starting the surgical procedure, conduct a final verification by at least two (2) members of the surgical team confirming the correct patient, surgery, site marking(s) and, as applicable, implants and special equipment or requirements. As a “fail -safe” measure, the surgical procedure is not started until any and all questions or concerns are resolved. Procedures done in non–operating room settings must include site marking for any procedures involving laterality, or multiple structures.	B C	**Interpretive Guidance:** The intent is to ensure patient safety. A time-out is the surgical team's short pause just before an incision to confirm that they are about to perform the correct procedure on the correct body part of the correct patient. The purpose of a systematic time-out is to refocus on the patient in the OR just before beginning a surgical procedure (i.e., just before the incision). A time-out can be performed easily, does not require any specific qualification or educational courses, can be repeated as many times as necessary, and costs nothing. Its mean duration has been measured to be 36 seconds, leaving no room for excuses for its omission, with the argument that it is time-consuming. Team member introductions help to promote team spirit during operation. Finally, pre-OR time-outs have been shown to significantly increase the rate of on-time first surgical starts. A time-out and a presurgical checklist are two (2) different processes. However, a time-out can be addressed in a presurgical checklist. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

			• Is corrective action taken when a discrepancy is identified? • Observe a time-out being performed by staff. **The WHO safer surgery checklist time out procedure revisited: Strategies to optimize compliance and safety** https://www.sciencedirect.com/science/article/pii/S174391911930158X **AANA Patient-Centered Perianesthesia Communication, 2023** https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication **AORN, Wrong Surgeries Up 26% in 2023** https://www.aorn.org/about-aorn/aorn-newsroom/periop-today-newsletter/periop-today-newsletter/wrong-surgeries-up-26--in-2023	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION H: Intra-Operative Anesthetic Monitoring and Documentation				
8-H-1	A qualified anesthesia professional shall be present in the OR/procedure room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care.	B C	**Interpretive Guidance:** The intent is to ensure patient safety. Qualified anesthesia staff shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care. Because patient status can change rapidly during anesthesia, qualified anesthesia staff shall continuously be present to monitor the patient and provide anesthesia care." (ASA) **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	
8-H-2	Clinical records must contain evidence of circulation monitored by continuous EKG during procedures.	416.47(b)(6) Standard B C	**Interpretive Guidance:** The intent is to ensure the adequacy of the patient's circulatory function during all anesthetics. Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location. It is not necessary to include an EKG strip in the clinical record. However, documentation must reflect continuous EKG monitoring and interpretation of the EKG. **Evaluating Compliance:** • Interview staff.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review clinical records for related documentation. • Observe practice. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/ **CMS standards Interpretive Guidance can be found at:**	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			SOM (cms.gov) Appendix L	
8-H-3	Clinical records must contain evidence of circulation monitored by blood pressure documented at least every five (5) minutes.	416.47(b)(6) Standard C	**Interpretive Guidance:** The intent is to ensure the adequacy of the patient's circulatory function during all anesthetics. Monitor and evaluate circulation to maintain the patient's hemodynamic status. Continuously monitor heart rate and cardiovascular status. Document blood pressure, heart rate, and respiration at least every five (5) minutes for all anesthetics. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_fo	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			r_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/ **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	
8-H-4	Clinical records must contain evidence of circulation monitored by heart rate documented at least every five (5) minutes.	416.47(b)(6) Standard B C	**Interpretive Guidance:** The intent is to ensure the adequacy of the patient's circulatory function during all anesthetics. Monitor and evaluate circulation to maintain the patient's hemodynamic status. Continuously monitor heart rate and cardiovascular status. Document blood pressure, heart rate, and	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			respiration at least every five (5) minutes for all anesthetics. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	
8-H-5	The clinical record must contain evidence of oxygenation and circulation monitoring by continuous pulse oximetry. When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the care team. Note: This standard does not apply if **only** topical and/or local anesthetic is used without the use of an oral premedication.	416.47(b)(6) Standard A B C	**Interpretive Guidance:** The intent is to ensure adequate oxygen concentration in the blood during all anesthetics. Continuously monitor oxygenation by clinical observation and pulse oximetry. During all anesthetics, excluding topical and local anesthesia without the use of an oral premedication, pulse oximetry shall be employed. When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the care team. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. • Check all alarms to determine if they are in working order.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA Documenting Anesthesia Care https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/ **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-H-9	Clinical records must contain evidence of temperature monitoring when clinically significant changes in body temperature are expected.	416.47(b)(6) Standard C	**Interpretive Guidance:** The intent is to aid in the maintenance of appropriate body temperature during all anesthetics. **Note:** This standard does not apply to procedures using local or minimal sedation, or procedures lasting less than 30 minutes. When clinically significant changes in body temperature are intended, anticipated, or suspected, body temperature must be monitored. Facility policies and procedures define what is considered clinically significant changes in body temperature from the patient's baseline temperature. Use active measures to facilitate normothermia. When MH triggering agents are present in the facility, monitor temperature and recognize signs and symptoms to immediately initiate appropriate treatment and management of MH. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Documenting Anesthesia Care**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/ **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-H-10	Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated.	C	**Interpretive Guidance:** The intent is to ensure adequate ventilation of the patient during all anesthetics. Continuously monitor ventilation by clinical observation, such as chest excursions, observation of the reservoir breathing bag, and auscultation of breath sounds. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	
8-H-11	Patient monitoring during anesthesia consists of end-ttidal carbon dioxide (ETCO2) sampling used on all moderate sedation, deep sedation or general anesthesia cases. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure, or equipment.	B C	**Interpretive Guidance:** The intent is to ensure adequate ventilation of the patient during moderate sedation, deep sedation, and general anesthesia. Continuously monitor ventilation by clinical observation and confirmation of continuous expired carbon dioxide during moderate sedation, deep sedation, or general anesthesia. Verify intubation of the trachea or placement of another artificial device by auscultation, chest excursion, and confirmation of expired carbon dioxide. Use ventilatory monitors as indicated. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure, or equipment. In such cases, the rationale for invalidating the need for end-tidal carbon dioxide	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			monitoring must be fully documented in the clinical record. ETCO2 levels are not actually being monitored when using a nasal cannula. Noting the positive presence of CO2 is actually more valid than the documentation of the number. The actual measurement of the CO2 is only accurate with an advanced airway, such as an endotracheal tube or supraglottic airway is in use. For example, if 4L of O2 is being delivered via a nasal cannula, or if a nitrous oxide nasal hood is being used in dentistry, the typical values of the ETCO2 will be 10-20 mm HG due to the dilution of the exhaled CO2 by the fresh gas flow. Documentation of ETCO2 at these levels is inaccurate and implies that the patient is being hyperventilated. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. The value of ETCO2 monitoring should be documented. It is not sufficient to only document using a positive (+) sign when an advanced airway is used. • Observe practice. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA Standards for Nurse Anesthesia Practice https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	
8-H-12	When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas and documented in the clinical record. Continual end-tidal carbon dioxide (ETCO2) analysis, in use from the time of endotracheal tube/laryngeal mask placement until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry, or mass spectroscopy. When capnography or capnometry is	C	**Interpretive Guidance:** To ensure adequate ventilation of the patient during general anesthesia. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. • Check all alarms to determine if they are in working order.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
	utilized, the end-tidal carbon dioxide alarm shall be audible to the Anesthesiologist or the anesthesia professional.		**AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-H-13	If an anesthesia machine is used during general anesthesia, the anesthesia machine must have an alarm for low O2 concentration.	C	**Interpretive Guidance:** The intent is to ensure adequate ventilation of the patient during general anesthesia. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. • Check all alarms to determine if they are in working order. **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	
8-H-15	An anesthesia record is maintained in which all medications given to a patient are recorded, including date, time, amount, and route of administration.	416.47(b)(6) Standard A B C	**Interpretive Guidance:** The intent is to ensure that the intra-procedure anesthesia record reflects the medications administered. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA Standards for Nurse Anesthesia Practice https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring **ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-H-16	An anesthesia record is maintained in which all intravenous fluids given intra-operatively are recorded.	416.47(b)(6) Standard B C	**Interpretive Guidance:** The intent is to ensure that the intra-procedure anesthesia record reflects the administration of intravenous fluids. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L **AANA Documenting Anesthesia Care** https://issuu.com/aanapublishing/docs/4_-_documenting_anesthesia_care?fr=sNDZlYTU2NDAxMjU **AANA Standards for Nurse Anesthesia Practice** https://issuu.com/aanapublishing/docs/standards_for_nurse_anesthesia_practice_2.23?fr=sOGNhNjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists https://pubs.asahq.org/anesthesiology/article/96/4/1004/39315/Practice-Guidelines-for-Sedation-and-Analgesia-by **Intraoperative Phase, 2023** https://nurseslabs.com/intraoperative-phase/	
SUB-SECTION I: Transfer to Post-Anesthesia Care Unit (PACU)				
8-I-1	The operating room may be used for patient recovery if only one (1) operation is scheduled that same day, or if the recovering patient meets all discharge criteria prior to beginning the next operation, or if there is another operating room available for the next operation.	B C	**Interpretive Guidance:** The intent is to permit patient recovery in the operating room if the criteria in the standard are met. However, a post anesthesia care unit is still required. This standard does not negate the need for a PACU when required by standards or regulations. See standards 2A2 and 2A3 which require a PACU When the operating room is used for patient recovery, all of the PACU standards apply. See standards 2D1,4D1, 4D2, and 5B2. **Evaluating Compliance:** • Tour facility. • Review facility floor map. • Interview staff. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-I-2	Patients transferred to the PACU will be continually evaluated and monitored as needed during transport.	B C	**Interpretive Guidance:** The intent is to ensure that patients are evaluated and monitored as needed during transport to the PACU. If the patient is recovered in the OR, the recovery time and hand off are documented. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Patient-Centered Perianesthesia Communication, Transfer of Care** https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication?fr=sNTcwZjU2NDAxMjU	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-I-3	Patients transferred to the PACU are accompanied by an anesthesia professional who is knowledgeable about the patient.	B C	**Interpretive Guidance:** The intent is to ensure that an anesthesia professional accompanies the patient to the PACU. The facility policies and procedures identify where and how this is documented in the clinical record. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Patient Centered Perianesthesia Communication, Transfer of Care** https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication?fr=sNTcwZjU2NDAxMjU **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-I-4	Patient transfer to the PACU will include the transmission of a verbal report on the patient to the PACU nurse accepting care of the patient from the anesthesia professional who accompanies the patient to the PACU. The clinical record must include documentation that the verbal report was completed.	B C	**Interpretive Guidance:** The intent is to ensure continuity of care and the transfer of responsibility and accountability for the patient by providing a clear and complete verbal report to the PACU nurse who accepts care of the patient. Poor communication may jeopardize patient safety. The anesthesia professional accurately reports the patient's condition, including all essential information, and transfers the responsibility of care to another qualified healthcare provider in a manner that assures continuity of care. Upon arrival in the PACU, the patient should be re-evaluated, and a verbal report should be provided to include the patient's status and information concerning the perioperative condition and surgical/anesthetic course. A member of the anesthesia care team remains in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient. The facility addresses the critical elements of the verbal report. For example, the following table contains a PACU Handoff tool that a facility may choose to use. Use of this tool is not required.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments

Figure 1. PACU Handoff Checklist

Patient	Patient Identification (Nameband check)	
	Time In	
	Allergies	
	Surgical Procedure and Reason for Surgery	
	Type of Anesthesia (GA, TIVA, regional)	
	Surgical or anesthetic complications	
	PMH and ASA Scoring	
	Preoperative Cognitive Function	
	Preoperative Activity Level (METs)	
	Limb Restriction	
	Preop Vitals	
Procedure	Positioning of Patient (if other than supine)	
	Intubation conditions (grade of view, airway, quality of bag mask ventilation, bite block?)	
	Lines/catheters (IVs, a-lines, CVSs, foley chest tubes, surgical drains, VP shunt)	
	Fluid Management	Fluids= EBL= UO=
Medications	Analgesia Plan - During Case, Postop Orders	
	Antiemetics Administered	
	Medications due during PACU (antibiotics, etc.)	
	Other Intra-Op Medications (steroids, antihypertensives)	

"Do you have any questions or concerns?"

Evaluating Compliance:

- Interview staff.
- Review clinical records for related documentation.
- Observe practice, if possible.

AANA Patient Centered Perianesthesia Communication, Transfer of Care
https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication?fr=sNTcwZjU2NDAxMjU

AHRQ Tool: Handoff, 2023

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.ahrq.gov/teamstepps-program/curriculum/communication/tools/handoff.html **APSF Improving Post Anesthesia Care Unit (PACU) Handoff by Implementing a Succinct Checklist** https://www.apsf.org/article/improving-post-anesthesia-care-unit-pacu-handoff-by-implementing-a-succinct-checklist/ **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	
8-I-5	Patient transfer to the PACU will include the transfer of information concerning the preoperative condition of the patient, the invasive procedure, related medication, and the anesthesia course.	B C	**Interpretive Guidance:** The intent is to ensure the safe and complete transfer of information when the patient is moved to the PACU. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **AANA Patient-Centered Perianesthesia Communication, Transfer of Care**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication?fr=sNTcwZjU2NDAxMjU **AHRQ Tool: Handoff, 2023** https://www.ahrq.gov/teamstepps-program/curriculum/communication/tools/handoff.html **APSF Improving Post Anesthesia Care Unit (PACU) Handoff by Implementing a Succinct Checklist** https://www.apsf.org/article/improving-post-anesthesia-care-unit-pacu-handoff-by-implementing-a-succinct-checklist/ **ASA Standards for Basic Anesthetic Monitoring, 2020** https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-I-6	Patient transfer to the PACU will include an anesthesia professional remains in the post-anesthesia area until the post-anesthesia care nurse accepts responsibility for the patient. .	B C	**Interpretive Guidance:** The intent is to ensure continuity of care and the transfer of responsibility and accountability for the patient until the care has been turned over to the PACU nurse who accepts care of the patient. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice, if possible. **AANA Patient-Centered Perianesthesia Communication, Transfer of Care** https://issuu.com/aanapublishing/docs/9_-_patient-centered_perianesthesia_communication?fr=sNTcwZjU2NDAxMjU **AHRQ Tool: Handoff, 2023** https://www.ahrq.gov/teamstepps-program/curriculum/communication/tools/handoff.html **APSF Improving Post Anesthesia Care Unit (PACU) Handoff by Implementing a Succinct Checklist** https://www.apsf.org/article/improving-post-anesthesia-care-unit-pacu-handoff-by-implementing-a-succinct-checklist/	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			ASA Standards for Basic Anesthetic Monitoring, 2020 https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring	
SUB-SECTION J: Post-Anesthesia Care Unit (PACU) Documentation				
8-J-1	PACU documentation includes patient's time of arrival in the PACU, or when recovery time started if the patient is recovered in the OR.	B C	**Interpretive Guidance:** The intent is to ensure the safe arrival of the patient to PACU and to document the start time of the recovery phase. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-J-2	The patient's post-surgical condition must be assessed and documented in the clinical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post- operative care experience in accordance with applicable State health and safety laws, standards of practice, and facility policy.	416.52(b)(1) Standard A B C	**Interpretive Guidance:** Except for the assessment of the patient's recovery from anesthesia, the post-surgical condition assessment may be performed by a physician, another qualified practitioner, or a registered nurse with post-operative care experience who is permitted, under applicable State laws as well as general standards of practice	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			and the facility's clinical policy, to assess patients postoperatively.. . **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	
8-J-4	PACU documentation includes a record of all medications given to a patient, including date, time, dose, and route of administration.	B C	**Interpretive Guidance:** The intent is to ensure the safe administration and documentation of medications administered. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-J-5	PACU documentation includes a record in which all intravenous and subcutaneous fluids given post- operatively are recorded.	B C	**Interpretive Guidance:** The intent is to ensure the safe administration and documentation of IV fluids administered. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-J-6	PACU documentation includes a record of monitoring and assessment of: - post-operative vital signs, including temperature, heart rate, respirations, and blood pressure; - mental status; - airway patency, ventilation, and oxygen saturation; and, - pain, nausea and vomiting, hydration, drainage, and bleeding, as applicable. Patient status is recorded until the patient is discharged from the facility.	B C	**Interpretive Guidance:** Post-anesthesia monitoring and assessment aim to improve outcomes for patients who have just received anesthesia, sedation, or analgesia care. PACU documentation can be done in various ways, as defined by the facility policies and procedures. Examples include the use of a form or tool, progress notes, and nurses' notes. Post-anesthesia monitoring and assessment apply to patients of all ages who have just received general anesthesia, regional anesthesia, or moderate or deep sedation and are expected to be individualized according to patient needs. The facility addresses the level and frequency of monitoring once the patient has met discharge criteria from the PACU and is simply waiting for a ride.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Interview staff. • Review clinical records for related documentation. • Observe practice. **Standards for Postanesthesia Care, 2019** https://www.asahq.org/standards-and-practice-parameters/standards-for-postanesthesia-care **Practice Guidelines for Postanesthetic Care: An Updated Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care** https://pubs.asahq.org/anesthesiology/article/118/2/291/13600/Practice-Guidelines-for-Postanesthetic-CareAn	
8-J-9	Post-operative progress notes are recorded.	A B C	**Interpretive Guidance:** The intent is to ensure complete documentation of the post-operative phase of care. PACU documentation can be done in various ways, as defined by the facility policies and procedures. Examples include the use of a form or tool, flow sheets, progress notes, and nurses' notes. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Observe practice.	
8-J-10	There is a procedure/operative report completed by the surgeon/proceduralist, which includes procedure technique and findings.	A B C	**Interpretive Guidance:** The intent is to ensure a complete procedure report/operative note is documented in the clinical record. The surgeon/proceduralist may document the patient's postoperative status as part of the procedure report/postoperative note. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION K: Discharge				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-K-1	Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.	416.52(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-K-2	All clinical records must include a discharge diagnosis.	416.47(b)(8) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-K-3	Post-surgical needs must be addressed and included in the discharge notes.	416.52(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-K-4	Approved and standardized discharge criteria are used and recorded (e.g. Aldrete score).	B C	**Interpretive Guidance:** The intent is to ensure that the patient is safely discharged. Aldrete's scoring system is a commonly used scale for determining when postsurgical patients can be safely discharged from the post-anesthesia care unit, generally to a second-stage recovery area, hospital, or home. A facility is not required to utilize the Aldrete scoring system. Instead, it may use a comparable tool outlined in its policies and procedures to determine patient readiness for discharge. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice. **Aldrete's Scoring System** https://en.wikipedia.org/wiki/Aldrete's_scoring_system **Practice Guidelines for Postanesthetic Care: An Updated Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://pubs.asahq.org/anesthesiology/article/118/2/291/13600/Practice-Guidelines-for-Postanesthetic-CareAn	
8-K-5	Before discharge, a physician or an anesthetist as defined at 42 CFR 410.69(b), in accordance with applicable State health and safety laws, standards of practice, and ASC policy, must evaluate each patient for proper anesthesia recovery. The physician's or anesthetist's name must be noted on the patient record. This standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.	416.42(a)(2) Standard B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-K-7	Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.	416.52(c)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-K-8	Written discharge instructions, including procedures for emergency situations, are given to the responsible adult who is responsible for the patient's care and transportation following a procedure. A signed copy of the instructions by the responsible adult is maintained in the patient's chart. The standard does not apply if **only** topical and/or local anesthetic is used without the use of an oral premedication.	A B C	**Interpretive Guidance:** The intent is to ensure that a responsible adult receives complete discharge instructions to support the patient's safe recovery. The importance of providing adequate discharge instructions to communicate with patients and primary care physicians cannot be overstated. All discharge instructions must be in writing, and a copy should be provided to the patient's primary care provider. Generally, discharge instructions address the following: discharge diagnosis, follow-up appointments, contact numbers in case of emergency, diet, activity level, level of supervision needed, wound care, specific actions the patient should take in the immediate post-discharge period to promote their recovery from the surgery (wound care, application of heat/cold, warning signs of complications), pre-operative medications	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			and prescriptions, and when driving is permitted. Medication instructions should also address when to resume pre-operative medications and new prescriptions. Age is not the only factor in determining whether an individual is a responsible adult. A responsible adult is an individual who is capable of providing post-procedure care at home and reporting any post-procedure or post-anesthesia complications that may be considered for inclusion in the facility's policies and procedures. Patients are increasingly taking Uber, Lyft, cab, or another transportation source to go home. The facility must have clear written policies regarding patient discharge and notify patients of these requirements. Should a patient insist on taking Uber, Lyft, or a cab, the facility must document the patient's willful deviation from the facility's policies in the patient's clinical record and have a staff member assist the patient to the vehicle. In such a case, discharge instructions are given to the patient and signed by the patient. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			AANA position paper - Discharge After Sedation or Anesthesia on the Day of the Procedure: Patient Transportation With or Without a Responsible Adult https://issuu.com/aanapublishing/docs/8_-_discharge_after_sedation_or_anesthesia_on_the_?fr=sOTE3YjU2NDAxMjU **Practice Guidelines for Postanesthetic Care: An Updated Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care** https://pubs.asahq.org/anesthesiology/article/118/2/291/13600/Practice-Guidelines-for-Postanesthetic-CareAn **Legal Update: The Ride Home: Uber Complicated or Easy Lyft?** https://www.aorn.org/outpatient-surgery/article/2019-February-legal-update-the-ride-home-uber-complicated-or-easy-lyft	
8-K-9	Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedures or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow up care.	416.52(c)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-K-10	Patients receiving anesthetic agents other than topical or local anesthesia must be supervised in the immediate post-discharge period by a responsible adult for at least 12 to 24 hours, depending on the procedure and the anesthesia used.	B C	**Interpretive Guidance:** The intent is to support patient safety after discharge. Patients are increasingly taking Uber, Lyft, cab or another transportation source to go home. The facility must have clear written policies regarding patient discharge and notify patients of these requirements. Should a patient insist on taking Uber, Lyft or cab, the facility must document the patient's knowing and willful deviation from the facility's policies in the patient's clinical record and have a staff member assist the patient to the vehicle. In such a case, discharge instructions are given to the patient and signed by the patient. **Evaluating Compliance:** • Interview staff. • Review clinical records for related documentation. • Observe practice.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION L: Operative Log				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-L-1	A separate dated operative log of all cases is maintained, either in a sequentially numbered, bound journal from which pages may not be removed, or in a tamper-proof, secured computer record consistent with state and federal law. This log must be kept in the facility.	A B C	**Interpretive Guidance:** The intent is to ensure that surgical case information, including the information specified in this section, is collected and tracked on all cases done in the facility as part of quality management activities. The log may be in electronic or paper format. Measures are taken to ensure its security and tamper-proofness. Electronic logs are password-protected with limited access and are not required to be sequentially numbered. A professionally bound spiral book is acceptable. **Evaluating Compliance:** • Interview staff. • Review the operative log for required documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-L-3	An operative log must include the date of procedure.	A B C	**Interpretive Guidance:** The intent is to maintain a complete and accurate accounting of all surgical cases performed in the facility. **Evaluating Compliance:** • Interview staff. • Review the operative log for required documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Observe practice.	
8-L-4	An operative log must include the patient's name and date of birth or other identification number.	A B C	**Interpretive Guidance:** The intent is to maintain a complete and accurate accounting of surgical cases. Two (2) patient identifiers are needed to ensure proper patient identification. **Evaluating Compliance:** • Interview staff. • Review the operative log for required documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-L-6	An operative log must include the surgeon/proceduralist's name.	A B C	**Interpretive Guidance:** The intent is to maintain a complete and accurate accounting of surgical cases. **Evaluating Compliance:** • Interview staff. • Review the operative log for required documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-L-7	An operative log must include a record of the type of anesthesia used.	416.47(b)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
8-L-8	An operative log must include the name of person(s) administering anesthesia.	416.47(b)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
8-L-9	An operative log must include the name of person(s) assisting physician (e.g. additional physician, registered nurse - circulating or scrubbed, scrub tech, physician's assistant, dental assistant, anesthesia assistant, or other qualified personnel).	A B C	**Interpretive Guidance:** The intent is to maintain a complete and accurate accounting of surgical cases. **Evaluating Compliance:** • Interview staff. • Review the operative log for required documentation. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 9: GOVERNING BODY

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Governing Body				
9-A-0	Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of 416.2. ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.	416.2 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
	Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure.			

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-1	The facility has a governing body with full legal responsibility for determining, implementing, and monitoring policies governing facility's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.	416.41 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-2	The medical and clinical staff of the ASC must be accountable to the governing body.	416.45 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-3	The minutes of each official "Governance" meeting are recorded and filed with the original governing rules and regulations.	A B C	**Interpretive Guidance:** The intent is to ensure that documentation of each meeting is maintained. The facility policies and procedures identify the frequency of leadership meetings. Quarterly meetings are recommended, but meetings should occur no less than annually. **Evaluating Compliance:** • Interview staff.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review the governing body meeting minutes.	
9-A-4	The appointment of clinical and administrative personnel is documented.	A B C	**Interpretive Guidance:** The intent is to ensure that appointments are documented and maintained. The term "appointments" in this context includes all staff. Medical staff are appointed, and other staff are hired. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Review leadership meeting minutes for appointments of medical staff, including advanced practice RNs.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-5	The governing body/facility leadership has defined the scope and intended use of the facility, as well as the appropriate ancillary support needed for the intended surgical procedures.	A B C	**Interpretive Guidance:** The intent is to ensure that the scope of services and use of the facility are defined based on its resources. Ancillary resources include the expertise of the staff and staffing levels, as well as the space and equipment resources to support the services offered. **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Interview staff. • Review governing body meeting minutes.	
9-A-6	The rules and regulations of the governing body are reviewed and revised at least annually.	A B C	**Interpretive Guidance:** The intent is to ensure rules and regulations are reviewed regularly and updated as needed. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-7	The governing body/facility leadership: Is regulated by a governing document that has the consent of each member of the body.	A B C	**Interpretive Guidance:** The intent is to ensure that all members of the governing body agree on the roles and responsibilities outlined in the bylaws document. **Evaluating Compliance:** • Review the facility's governing document. • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-8	The governing body/facility leadership: Has a policy for addressing potential conflicts of interest.	A B C	**Interpretive Guidance:** The intent is to ensure accountability of the governing body for identifying and addressing internal and external potential conflicts of interest. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-9	The governing body/facility leadership: Assumes full responsibility for reviewing and taking appropriate action on legal affairs of the ASC and its staff.	A B C	**Interpretive Guidance:** The intent is to ensure accountability of the governing body. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-10	The governing body/facility leadership: Sets policy on how individual staff deal with each other and external parties.	A B C	**Interpretive Guidance:** The intent is to ensure that the governing body develops policies and procedures that develop and maintain accountability of facility staff behavior. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes. • Observe staff interactions with each other and outside parties.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-11	The governing body/facility leadership: Sets policy on staff's role in properly dealing with patients.	A B C	**Interpretive Guidance:** The intent is to ensure that the governing body develops policies and procedures that establish expectations and maintain accountability for the facility staff on customer service. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes. • Observe staff interactions with patients.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-12	The governing body/facility leadership is responsible for the operation and performance of the facility including: Determining the mission and goals of the facility, including the types of services provided and for determining, implementing, and monitoring policies governing the facility's total operation.	A B C	**Interpretive Guidance:** The intent is to ensure accountability of the governing body for the operation and performance of the facility. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-13	The governing body is responsible for the operation and performance of the ASC including: Determining the organizational structure.	A B C	**Interpretive Guidance:** The intent is to ensure the accountability of the governing body for determining the organizational structure of the facility, **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes. • Review the facility organizational chart.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-14	The governing body/facility leadership is responsible for the operation and performance of the ASC including: Adopting policies and procedures for the orderly conduct of the ASC and for insuring procedures are provided in a safe and effective manner.	A B C	**Interpretive Guidance:** The intent is to ensure accountability of the governing body that policies and procedures for the orderly conduct of the ASC and for ensuring procedures are provided in a safe and effective manner have been developed and implemented. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-15	The governing body/facility leadership is responsible for the operation and performance of the ASC including: Ensuring financial responsibility.	A B C	**Interpretive Guidance:** The intent is to ensure the accountability of the governing body for ensuring financial responsibility. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-A-16	The governing body/facility leadership is responsible for the operation and performance of the ASC including: Approving all arrangements for ancillary medical care delivered in the ASC, including laboratory, radiological, pathologic and anesthesia services.	A B C	**Interpretive Guidance:** The intent is to ensure the governing body's accountability for approving all arrangements for ancillary medical care delivered in the ASC, including laboratory, radiological, pathologic, and anesthesia services. The governing body/facility leadership is not necessarily one (1) person. Often, more than one (1) person makes up the governing board/facility leadership.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Although the governing body is ultimately responsible and accountable for these policies and procedures, medical staff, anesthesia professionals, and nursing staff should be involved in specifying the types of emergency equipment required for use in the organization's operating room. **Evaluating Compliance:** • Interview staff. • Review contracts for contracted ancillary services. • Review governing body meeting minutes.	
9-A-17	The governing body/facility leadership must assure that all outside services are provided in a safe and effective manner.	416.41(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-18	The governing body is responsible for the operation and performance of the ASC including: Complying with the Equal Employment Opportunities Act and with the Americans with Disabilities Act.	A B C	**Interpretive Guidance:** The intent is to ensure accountability of the governing body. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes. • Observe staff for evidence of issues related to compliance with the Equal Employment Opportunities Act and with the Americans with Disabilities Act.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-A-19	The governing body of the facility coordinates, develops, and revises the organization's policies and procedures to specify the types of emergency equipment required for use in the organization's operating room.	A B C	**Interpretive Guidance:** The intent is to ensure the accountability of the governing body that the facilities policies and procedures address the types of emergency equipment required for use in the organization's operating room. Although the governing body is ultimately responsible and accountable for these policies and procedures, medical staff, anesthesia professionals, and nursing staff should be involved in specifying the types of emergency equipment required for use in the organization's operating room. **Evaluating Compliance:** • Interview staff. • Review governing body meeting minutes. • Are the types of emergency equipment present in the operating room consistent with the governing body specifications?	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION B: Transfer Agreement				
9-B-1	The facility must provide the local hospital with written notice of its operations and patient population served upon opening and at least bi-annually.	416.41(b)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-B-3	The facility must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the facility.	416.41(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-B-4	This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under 42 CFR 482.2.	416.41(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: Extended Stays				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
9-C-1	The facility does not perform cases that ordinarily would take more than 24 hours from the time of the patient's admission to the time of recovery and discharge from the facility. Total patient time in the facility cannot extend beyond 23 hours and 59 minutes. If overnight stays are permitted, the facility is in compliance with all applicable local and state laws and regulations.	B C	**Interpretive Guidance:** The intent is to limit the need for an overnight patient stay in the facility. QUAD A does not dictate the length of surgery that can be performed in the office. However, the general recommendations for safe outpatient surgery involve surgical time limits of four (4) to six (6) hours for a general anesthesia case. If the procedure exceeds this time limit, it may be more appropriate to perform the surgery in a hospital setting. Some states put a time limit on surgery length for the outpatient setting. Check state requirements. A facility must outline the types of procedures and length of procedures to be performed within the facility. Patients admitted to the facility are permitted to stay 23 hours and 59 minutes, starting from the time of admission. The time calculation begins with the admission and ends with the discharge of the patient from the facility after the surgical procedure. While the time of admission normally would be the time of registration or check-in of the patient at the facility's reception area, for the purposes of compliance with this requirement facilities may use the time when the patient moves from the waiting/reception area into another part of the facility. This time must be documented in the	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			patient's medical record. The discharge occurs when the physician has signed the discharge order, and the patient has left the recovery room. Other starting or end points, e.g., time of administration of anesthesia or time the patient leaves the OR, may not be used to calculate compliance with the 24-hour requirement. Whichever definition a facility uses, the patient's recovery time must be considered. The patient's total time in the facility must stay under 23 hours and 59 minutes. In addition, the required staff, including a physician, must be available to monitor the patient's recovery until the patient is discharged from the facility. Rare instances of patients whose length of stay in the facility exceeds 24 hours do not automatically result in a deficiency. It is possible for an individual case to take longer than expected, due to unforeseen complications or other unforeseen circumstances. In such rare cases the facility continues to be responsible for the care of the patient until the patient is stable and able to be discharged in accordance with the regulatory requirements governing discharge, as well as the facility's policy. However, if a facility has cases exceeding 24 hours more than occasionally, this might suggest that the facility is not in compliance and would be cited as a deficiency.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Interview staff. • Review clinical records for related documentation. • Review operative log. • Observe practice.	
SUB-SECTION D: Laboratory Services				
9-D-1	If the facility provides laboratory services, the laboratory must meet the requirements of part 493 of 42 CFR. OR If the facility does not provide laboratory services, any referral laboratory must be certified in the appropriate specialties and sub-specialties of service to perform the referred tests in accordance with the requirements of part 493 of 42 CFR. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter of the Code of Federal Regulations.	416.49(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
9-D-2	The ambulatory surgery facility's policies and procedures must list the kinds of laboratory services that are provided directly by the facility and services that are provided through a contractual agreement.	A B C	**Interpretive Guidance:** The intent is to discriminate between laboratory services provided directly or through a contractual agreement. **Evaluating Compliance:** • Interview staff. • Review the list of laboratory services provided directly or via a contractual	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			agreement for completeness and accuracy.	

SECTION 10: QUALITY ASSESSMENT / QUALITY IMPROVEMENT / RISK MANAGEMENT

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Quality Assessment / Quality Improvement Program / Risk Management				
10-A-1	A licensed and qualified anesthesia professional supervising or providing care in the facility must participate in quality assessment/quality improvement and risk management in the facility.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Quality Improvement Program				
10-B-1	The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.	416.43 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	
10-B-2	The facility has a written quality improvement program implemented which includes surveys or projects to: - Monitor and evaluate patient care - Evaluate methods to improve patient care - Identify and correct deficiencies within the facility - Alert the facility's Quality Improvement Program to identify, track, trend, evaluate and resolve problems.	A B C	**Interpretive Guidance:** The intent is to ensure a written quality improvement program is implemented that includes surveys or projects. **Evaluating Compliance:** • Review the written quality improvement program. • Interview staff and review the written quality improvement program. • Are staff able to discuss the quality improvement program and the surveys or projects implemented to monitor and evaluate care? • Are deficiencies identified and corrected? Are staff able to identify these deficiencies and corrections? • Review quality improvement program and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-6	The facility has a written quality improvement program that includes documentation of Peer Review meetings for the prior three (3) years, which must be available for the surveyor. Facilities with a monthly case volume of 50 or fewer cases must conduct peer review meetings no less than twice per year. Facilities with a monthly case volume in excess of 50 cases must conduct peer review meetings no less than quarterly. The minimum sample size is 10% of the monthly case volume.	A B C	**Interpretive Guidance:** The intent is for the facility to demonstrate how the quality improvement program identifies and tracks peer review meetings. **Evaluating Compliance:** • Review the written quality improvement program. • Interview staff. • Validate the facility's monthly case volume. Based on the case volume, are peer review meetings conducted at least twice a year or quarterly? • Review quality improvement program, leadership, and peer review meeting minutes	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-7	The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.	416.43(a)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-8	The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.	416.43(a)(2) Standard A C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-9	The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.	416.43(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-10	The ASC must use the data collected to monitor the effectiveness and safety of its services, and quality of its care.	416.43(b)(2) Standard 416.43(b)(2)(i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			SOM (cms.gov) Appendix L	
10-B-11	The ASC must use the data collected to identify opportunities that could lead to improvements and changes in its patient care.	416.43(b)(2) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-12	The ASC must set priorities for its performance improvement activities that focus on high risk, high volume, and problem-prone areas.	416.43(c)(1) Standard 416.43(c)(1) (i) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			SOM (cms.gov) Appendix L	
10-B-13	The ASC must set priorities for its performance improvement activities that consider incidence, prevalence, and severity of problems in those areas.	416.43(c)(1) (ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-14	The ASC must set priorities for its performance improvement activities that affect health outcomes, patient safety, and quality of care.	416.43(c)(1) (iii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-15	Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.	416.43(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-16	The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.	416.43(c)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-17	The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.	416.43(d)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-18	The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.	416.43(d)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-19	The governing body must ensure that the QAPI program is defined, implemented, and maintained by the ASC.	416.43(e) Standard 416.43(e)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-20	The governing body must ensure that the QAPI program addresses the ASC's priorities and that all improvements are evaluated for effectiveness.	416.43(e)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-21	The governing body must ensure that the QAPI program specifies data collection methods, frequency, and details.	416.43(e)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-B-22	The governing body must ensure that the QAPI program clearly establishes its expectations for safety.	416.43(e)(4) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-B-23	The governing body must ensure that the QAPI program adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.	416.43(e)(5) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION D: Peer Review				
	Quality Assurance/Quality Improvement is comprised of several different processes including but not limited to Peer Review. Peer Review refers to periodic peer review of patient medical records by a peer physician. Additionally, QUAD A seeks to promote the best standards and safest possible practices through its Patient Safety Data Reporting process. Patient Safety Data Reporting falls under the broad umbrella of peer review but is a distinct process from the Peer Review process noted above and consists of the online submission of random cases and all adverse events in accordance with standards.			
10-D-1	To be HIPAA compliant, a copy of the HIPAA Business Associates Agreement must be signed by each physician working outside the facility participating in such facility's Quality Assurance/Quality Improvement process, including but not limited to Peer Review and Patient Safety Data Reporting, and a copy must be retained on file in the facility.	A B C	**Interpretive Guidance:** A HIPAA Business Associate Agreement is a contract between the facility and a business or individual that performs certain functions or activities on behalf of, or provides a service to, the facility when the function, activity, or service involves the creation, receipt, maintenance, or transmission of Protected Health Information (PHI) by the business or individual. The agreement establishes the permissible uses and disclosures of PHI by the business associate, how the business associate will	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			support patients' Privacy Rule rights, and the responsibilities of both parties to maintain the privacy and security of PHI. The agreement should also: • Stipulate that the business associate will not use or further disclose PHI other than as permitted by the contract or as required by law. • Require the business associate to implement appropriate safeguards to prevent unauthorized uses or disclosures of the PHI. • Require the business associate to report any use or disclosure not provided for by the agreement, including breaches of unsecured PHI. • Require the business associate to satisfy requests for copies of PHI, amendments to PHI, and accounting of disclosures. • Require the business associate to make records available relating to uses and disclosures of PHI in the event of an audit or investigation. • Require the business associate to return or destroy PHI received from, or on behalf of, the covered entity at the agreement's termination. • Require the business associate to ensure that any subcontractors with access to PHI agree to the same restrictions and	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			conditions that apply to the business associate. • Authorize the termination of the contract by the facility if the business associate violates any term of the agreement (and vice versa). **Evaluating Compliance:** • Interview staff. • Review a copy of the HIPAA Business Associate Agreement to determine completeness. • Review signed agreements to determine if all physicians working outside the facility participating in QAPI, including peer review and PSDR, have signed agreements on file **Business Associate Contracts** https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html **Covered Entities and Business Associates** https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html **Model BAA** https://www.hhs.gov/sites/default/files/model-business-associate-agreement.pdf	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			HIPAA Business Associate Agreement https://www.hipaajournal.com/hipaa-business-associate-agreement/ **QUAD Sample BAA** https://6276684.fs1.hubspotusercontent-na1.net/hubfs/6276684/Applications/HIPAA%20BAA%202022%20122021-2.pdf	
10-D-2	If peer review sources external to the facility are used to evaluate the delivery of medical care, the HIPAA Business Associates Agreement is so written as to waive the confidentiality of the clinical records.	A B C	**Interpretive Guidance:** The intent is to ensure the confidentiality of clinical records and PHI. **Evaluating Compliance:** • Interview staff. • Review a copy of the HIPAA Business Associates Agreement to determine completeness. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-D-3	Peer review may be done by a recognized peer review organization or a surgeon/proceduralist other than the operating surgeon/proceduralist, unless otherwise specified by state regulations.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Interview staff. • Validate that the required organization or like-surgeon/proceduralist(s) other than the operating surgeon/proceduralist is performing peer review unless otherwise specified by state regulations. • Review quality improvement program, peer review, and leadership meeting minutes. • If Peer Review is not being conducted at all, this standard is scored deficient.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-D-4	Peer review and the associated peer review meetings should include at a minimum the same random cases and adverse events submitted to the Patient Safety Data Reporting since the preceding peer review meeting.	A B C	**Interpretive Guidance:** The intent is to ensure that the minimum elements of peer review are addressed. Peer review and Patient Safety Data Reporting are two (2) separate and independent processes. The facility must define in its policies and procedures which cases, outside the minimum random cases and reported adverse events, Peer Review must be conducted. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review Patient Safety Data Reporting. • Review quality improvement program, peer review, and leadership meeting minutes.	
10-D-5	Peer review must include at a minimum: Record of the adequacy and legibility of history and physical exam	A B C	**Interpretive Guidance:** The intent is to ensure that in each clinical record where Peer Review is conducted, there is a review of a history and physical has been adequately performed and that if it is handwritten, and readable. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-D-6	Peer review must include at a minimum: Record of the adequacy of surgical consent	A B C	**Interpretive Guidance:** The intent is to ensure that in each clinical record where Peer Review is conducted, there is a review that there is a properly executed informed consent. **Evaluating Compliance:** • Interview staff.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	
10-D-7	Peer review must include at a minimum: Record of the adequacy of appropriate laboratory, EKG, and radiographic reports	A B C	**Interpretive Guidance:** The intent is to ensure that each clinical record where Peer Review is conducted there is a review that the appropriate laboratory, EKG, and radiology reports are in clinical record as required by the patient's condition and they type of procedure performed. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-D-8	Peer review must include at a minimum: Record of the adequacy of a written operative report	A B C	**Interpretive Guidance:** The intent is to ensure that in each clinical record where Peer Review is conducted, there is a record that a written operative report is present. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-D-9	Peer review must include at a minimum: Record of the adequacy of anesthesia and recovery records (with IV sedation or general anesthesia).	B C	**Interpretive Guidance:** The intent is to ensure that in each clinical record where Peer Review is conducted there is a record that when the patient received IV sedation or general anesthesia, the anesthesia and recovery documentation are accurate and complete. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
10-D-10	Peer review must include at a minimum: Record of the adequacy of instructions for post-operative care	A B C	**Interpretive Guidance:** The intent is to ensure that each clinical record where Peer Review is conducted has a copy of the post-operative care instructions present and that these instructions are appropriate for the procedure. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
10-D-11	Peer review must include at a minimum: Documentation of the discussion of any complications	A B C	**Interpretive Guidance:** The intent is to ensure that for each clinical record where Peer Review is conducted if there were complications, the Peer Review document contains documentation of the discussion of any complications. **Evaluating Compliance:** • Interview staff. • Review peer review documents to determine if all required elements are included. • Review quality improvement program, peer review, and leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 11: PERSONNEL

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Personnel				
11-A-1	If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.	416.45(c) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Medical Director & Facility Director				

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-B-1	The Medical Director must have an MD, DO, DPM, DMD, or DDS degree. A DPM may serve as the Medical Director only for facilities exclusively practicing podiatry. A DDS or DMD may serve as the Medical Director only for facilities exclusively practicing dentistry or oral maxillofacial surgery.	A B C	**Interpretive Guidance:** The intent is to ensure that the Medical Directors meet minimum requirements. **Evaluating Compliance:** • Interview staff. • Review personnel files for documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-B-2	The **Facility Director** must have an MD, DO, DPM, DMD, DDS, or CRNA degree. *One person may fill both the Medical Director and Facility Director roles, or the roles can be filled by two separate people.*	A B C	**Interpretive Guidance:** The intent is to ensure that the Facility Director meets minimum requirements. **Evaluating Compliance:** • Interview staff. • Review personnel files for documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-B-3	The Medical Director **and Facility Director** must be a provider currently licensed by the state in which the facility is located.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Interview staff. • Review personnel files for documentation.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-B-4	The Medical Director and Facility Director must be certified or eligible for certification by one of the following boards: • American Board of Medical Specialties (ABMS) • American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS) • American Board of Foot and Ankle Surgery (ABFAS) • American Board of Podiatric Medicine (ABPM) • National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA) (Facility Director only) • American Board of Pediatric Dentistry (ABPD) • American Board of Oral and Maxillofacial Surgery (ABOMS) • American Dental Board of Anesthesiology	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Interview staff. • Review personnel files for documentation	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-B-7	The Facility Director must be actively involved in the direction and management of the facility.	A B C	**Interpretive Guidance:** The intent is to ensure Facility Director participation in key areas of the facility operations. **Evaluating Compliance:** • Interview staff. • Review leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-B-8	The Facility Director is responsible for establishing and enforcing policies that protect patients. The Facility Director monitors all members of the medical and facility staff for compliance with this policy.	A B C	**Interpretive Guidance:** The intent is to ensure Facility Director participation in key areas of the facility operations. **Evaluating Compliance:** • Interview staff. • Review leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-B-9	The Medical Director must be involved in the organization's direction, objectives and policy development and implementation.	A B C	**Interpretive Guidance:** The intent is to ensure Medical Director involvement in key areas of facility operations. **Evaluating Compliance:** • Interview staff. • Review leadership meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: Surgeons / Proceduralists / Etc.				
11-C-1	Procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body in accordance with approved policies and procedures of the facility.	416.42 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-C-3	Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.	416.45(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-C-4	Medical staff privileges must be periodically reappraised by the ASC and the scope of procedures must be periodically reviewed and amended as appropriate.	416.45(b) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS standards Interpretive Guidance can be found at: SOM (cms.gov) Appendix L	
11-C-5	Each physician, advanced practice registered nurse and physician assistant including both directly employed and contract practitioners using the facility is credentialed and qualified for the procedures they perform.	A B C	**Interpretive Guidance:** The intent is to ensure **all** physicians, advanced practice RNs and PA including those directly employed and those under contract, are credentialed and qualified for the procedures they perform. The term "physician" includes **all** surgeons and anesthesiologists. Each physician who performs surgery or a procedure in the facility has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the facility. The facility's leadership is responsible for reviewing the qualifications of all physicians who have been recommended by qualified medical personnel and granting surgical privileges as the facility's leadership determines appropriate. **Fellows:** Fellows must be credentialed by the facility. A facility must also have a document outlining the	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			duties a Fellow is authorized by the facility leadership to perform/assist with. These duties are in accordance with approved policies and procedures. If the Fellow performs procedures independently, the Fellow would be considered part of the Medical Staff and must be fully credentialed and privileged. If the Fellow is not considered part of the Medical Staff and is not fully credentialed and privileged, the supervising physician must always be present when the Fellow is performing/assisting with any procedures/surgeries. Minimally, the facility must conduct primary source verification of licensure, education, and training. **Residents/Interns:** Residents/Interns are licensed practitioners and may assist with procedures under the direct supervision of licensed, credentialed, and privileged physicians providing care in the facility. Residents/Interns are not permitted to perform procedures independently. If a resident is doing a rotation as part of an approved graduate medical program education (GME) program, the facility must have a written agreement with the GME program. The agreement must address the resident's/intern's scope of practice at the facility and HIPAA requirements. There must be a signed business associate	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			agreement (BAA) between the GME program and the facility. If part of the GME program, the resident/intern does not need to sign a BAA. **Medical/Nursing Students:** Students are not licensed and may not perform or assist in procedures. Their role is observational only. If a student is doing a rotation as part of a medical/nursing school program, the facility must have a written agreement with the school, along with a signed BAA. The agreement must address the student's observational role at the facility. If part of a medical/nursing school program, the student does not need to sign a BAA. If a student is not in the facility as part of a medical/nursing school, a BAA is required. Minimally, the facility conducts primary source verification of education and training. **Evaluating Compliance:** • Review personnel files for related documentation. • Review facility contracts with academia institutions. • Observe practice if fellows, residents/interns or students are present in the facility.	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review leadership and credentialing and privileging meeting minutes. **Guidelines for Teaching Physicians, Interns, & Residents** www.cms.gov/files/document/guidelines-teaching-physicians-interns-and-residents.pdf	
11-C-6	The facility must have written policies and procedures that address the criteria for clinical staff privileges and the process that the facility's leadership body uses when reviewing physician, APRN, and PA credentials and determining whether to grant privileges and the scope of the privileges for each practitioner.	A B C	**Interpretive Guidance:** Each practitioner who performs surgery or procedures in the facility, including those directly employed and those under contract, has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the facility. The facility's leadership is responsible for reviewing the qualifications of all practitioners recommended by qualified medical personnel and granting surgical privileges as the facility's leadership determines appropriate. The medical staff includes physicians, surgeons, specialists, CRNAs, NPs, PAs, and allied health professionals, as identified in facility policy. **Evaluating Compliance:** • Interview staff. • Review personnel files to verify that medical staff have been granted clinical privileges. • Review leadership and peer review meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			CMS expands medical staff definition to include APRNs, PAs https://www.fiercehealthcare.com/healthcare/cms-expands-medical-staff-definition-to-include-aprns-pas	
11-C-7	Each physician, APRN, and PPA, including both directly employed and contracted practitioners, must currently be licensed by the state in which they practice. Electronic verification of each physician's current license or facility verification of licensure must be maintained on file in the facility. -	A B C	**Interpretive Guidance:** The term "physician" includes all surgeons and anesthesiologists, both directly employed and those under contract. For states that do not issue paper copies of licenses, a copy of the facility's verification must be kept in the personnel/credential file. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. **American Board of Medical Specialties, Verify Certification** https://www.abms.org/board-certification/verify-certification/ **Health Guide USA, Medical License Lookup** https://www.healthguideusa.org/medical_license_lookup.htm **National Council of State Boards of Nursing (NCSBN) Nurse Licensure Look Up**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.nursys.com/	
11-C-9	All individuals, including both directly employed and contract employees, using the facility must meet one of the following criteria: • A doctor of medicine currently certified, previously certified, or eligible for certification by one of the member boards of the American Board of Medical Specialties (ABMS). • A doctor of osteopathy currently certified, previously certified, or eligible for certification by the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS). • A podiatrist currently certified, previously certified, or eligible for certification by the American Board of Foot and Ankle Surgery (ABFAS) or The American Board of Podiatric Medicine (ABPM). • An oral and maxillofacial surgeon currently certified, previously certified, or eligible for certification by the American Board of Oral and Maxillofacial Surgery (ABOMS). •A nurse practitioner (NP) currently certified or eligible for certification with teh National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA). •A physician assistant (PA) with national certification.	A B C	**Interpretive Guidance:** The intent is to ensure practitioners providing care in the facility meet these minimum requirements. The goal is patient safety. A **Physician** is a licensed Doctor of Medicine or Osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and a Doctor of Dental Surgery or of Dental Medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his/her license. A **Certified Registered Nurse (CRNA)** is an Advanced Practice Registered Nurse (APRN) who has completed the required education and training to administer anesthesia and other medications, and possesses current licensure and certification as required by state law.	☐Compliant ☒Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			A **Nurse Practitioner (NP)** is an Advanced Practice Registered Nurse (APRN) who has completed the required nurse practitioner education: either a Master of Science in Nursing (MSN) or a Doctor of Nursing Practice (DNP). They can serve as either a primary or specialty care provider. Licensure requirements and scope of practice varies by state. A **Physician Assistant (PA)** is a licensed medical professional who holds an advanced degree and is able to provide direct patient care. They work with patients of all ages in virtually all specialty and primary care areas, diagnosing and treating common illnesses and working with minor procedures. Their supervising physician and state law determine the specific duties of a PA, but they provide many of the same services as a primary care physician. Advanced training is often required to specialize in a particular area. Typically, PAs will be required to complete a fellowship or residency in order to practice in a specialty or sub-specialty area. Additional training requirements, certifications, roles, and responsibilities vary between specialty areas and state scope of practice laws. The facility defines in policy the types of procedures that each NP and PA may perform in accordance with any specialty education and	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			training, state law, and scope of practice laws. This is documented in the personnel file. The glossary contains more detailed requirements for each of these roles. **Evaluating Compliance:** • Interview staff • Review personnel files for related documentation. • Review leadership and credentialing and privileging meeting minutes. **What's a Nurse Practitioner (NP)?** https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner **Physician Assistant** https://college.mayo.edu/academics/explore-health-care-careers/careers-a-z/physician-assistant/ **Become a PA** https://www.aapa.org/career-central/become-a-pa/ **American Association of Physician Assistants** https://www.aapa.org/career-central/become-a-pa/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-C-10	American Board of Medical Specialties (ABMS)-certified or eligible medical specialists who perform surgical procedures within the accredited facility may perform only those surgical procedures delineated in their ABMS board certification and/or covered by American Medical Association (AMA) Core Principle #7. American Osteopathic Association (AOA) certified or eligible physicians who perform surgical procedures within the accredited facility may perform only those surgical procedures delineated in their AOA board certification and/or covered by AMA Core Principle #7. Podiatrists certified or eligible for certification who perform surgical procedures with accredited facilities may perform only those surgical procedures delineated in their ABFAS board certification and/or covered by AMA Core Principle #7. The AMA Core Principle #7 (from AMA resolution dated April, 2003): AMA Core Principal #7—Physicians performing office-based surgery must be currently board certified/qualified by one of the boards recognized by the American Board of Medical Specialties, American Osteopathic Association, or a board with equivalent standards approved by the state medical board. The surgery must be one that is generally recognized by that certifying board as falling within the scope of training and practice of the physician providing the care.	A B C	**Interpretive Guidance:** The principles in this standard apply to both ABMS certified and eligible physicians. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Are physicians performing surgical procedures consistent with the privileges granted? • Review leadership and credentialing and privileging meeting minutes. **AMA Code of Ethics** https://code-medical-ethics.ama-assn.org/principles	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-C-11	Physicians, including both directly employed and contract physicians, who perform procedures, including anesthesia services, in facilities accredited by QUAD A must provide evidence of training and competence in the procedures for which the physician is credentialed and privileged to perform in the facility. Individual consideration will be given if the physician no longer possesses or cannot obtain such privileges, and can demonstrate that loss of, or inability to obtain such privileges was not related to lack of clinical competence, ethical issues, or problems other than economic competition. -OR- If the physician, including both directly employed and contract physicians, has never held privileges, or no longer holds privileges, QUAD A will accept alternate credentialing via primary source verification. Primary source verification must be performed every two (2) years. Additionally, these physicians who are being credentialed using primary source verification are not required to maintain hospital admitting privileges. Required elements of initial primary source verification are: • Verification of medical education directly from institution (MD, DO, DMD, DDS, or DPM degree) • Verification of any specialty/subspecialty from sponsoring institution • Verification of all state license(s) with issue date(s), expiration date(s), status (as of current date) and type of license (temporary, limited or unlimited) • Verification of board certification status, if applicable. • Drug Enforcement Administration (DEA) registration status • National Practitioner Databank (NPDB)'s Integrated	A B C	**Interpretive Guidance:** The intent is to ensure that physicians provide evidence of training and competency for which the physician is credentialed and privileged to perform in the facility. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Review leadership and credentialing and privileging meeting minutes.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
	Querying and Reporting Services (IQRS) results • Current malpractice insurance Required elements of ongoing primary source verification are: • Verification of all state license(s) with issue date(s), expiration date(s), status (as of current date), and type of license (e.g., temporary, limited or unlimited) •Verification of board certification status, if applicable •Drug Enforcement Administration (DEA) registration status •National Practitioner Databank (NPDB)'s Integrated Querying and Reporting Services (IQRS) Results •Current malpractice insurance			
11-C-12	Practitioners of interventional radiology must meet all of the following criteria: •MD or DO • Board certification or board eligibility by the American Board of Radiology (ABR) • Fellowship training as approved by the ABR • Current certificate of added qualifications in interventional/vascular radiology	A B C	**Interpretive Guidance:** The intent is to ensure practitioners of interventional radiology are trained and qualified to provide services. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Verify that qualified practitioners perform all interventional radiology procedures. • Review leadership and credentialing and privileging meeting minutes	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-C-13	Practitioners of Pain Management must meet all of the following criteria: - Have an M.D. or D.O. degree - Appropriate fellowship training in pain management - Possess ABMS Board certification in one of the following specialties: Anesthesiology, Physical Medicine and Rehabilitation (PM&R), Psychiatry/Neurology - Possess a sub-specialty certification from the American Board of Anesthesiology or the AOABOS - CRNAs, as permitted by state law, who have completed a one year academic pain fellowship accredited by the Council on Accreditation for Nurse Anesthesia Educational Programs and possess a subspecialty (non-surgical) board certification from the National Board for Certification and Recertification of Nurse Anesthetists.	A B C	**Interpretive Guidance:** The intent is to ensure practitioners of pain management are trained and qualified to provide services. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Verify that qualified practitioners perform all pain management procedures. • Review leadership and credentialing and privileging meeting minutes.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION D: Anesthesia Providers				
11-D-2	All anesthesia providers must be licensed or accredited by the state in which they practice.	B C	**Interpretive Guidance:** The intent is to ensure all anesthesia professionals are licensed. **Evaluating Compliance:** • Interview staff. • Review personnel files for related documentation. • Review leadership and credentialing and privileging meeting minutes.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-D-3	An anesthesia professional must be responsible for the administration of dissociative anesthesia with propofol, spinal or epidural blocks, or general anesthesia as well as the monitoring of all life support systems.	C	**Interpretive Guidance:** The intent is to ensure the safe administration of dissociative anesthesia with propofol, spinal or epidural blocks, or general anesthesia and monitoring of all life support systems. **Evaluating Compliance:** • Interview staff. • Review patient and anesthesia records for related documentation. • Observe practice.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
11-D-6	If responsible for supervising anesthesia or providing anesthesia, the qualified physician must be present in the operating suite throughout the administration of anesthesia.	B C	**Interpretive Guidance:** The intent is to ensure the safe administration of anesthesia through supervision by a physician qualified, trained, and privileged to administer anesthesia. **Evaluating Compliance:** • Interview staff. • Review personnel files to validate competency • Observe practice.	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-D-8	The anesthesia professional(s) cannot function in any other capacity (e.g., procedure assistant or circulating nurse) during the procedure, except for oral and maxillofacial surgery where the operator/anesthetist model has been established utilizing a two-person team for Moderate sedation and a three-person team for Deep sedation. All personnel must abide by all state and federal regulations and laws governing the administration of anesthesia.	B C	**Interpretive Guidance:** The intent is to ensure the safe administration of anesthesia. During the procedure, an anesthesia professional cannot function in any other capacity. The anesthesia professional is responsible for monitoring the patient during the procedure. Any qualified clinician who administers and monitors deep sedation must be dedicated to that task and different from the individual performing the diagnostic or therapeutic procedure. ASA recommends that those requesting privileges to provide deep sedation must be able to recognize in a timely manner that a patient has entered a state of general anesthesia and be able to maintain a patient's vital functions until appropriate recovery to a desired level of sedation or alertness. Further, it is recommended that the granting, appraisal, and revision of these clinical privileges be awarded on a procedure-specific and time-limited basis that accounts for the type and complexity of the procedures the qualified person may administer in accordance with the rules and regulations of the health care facility, and local, state, and federal governmental agencies. **Dental and Oral and maxillofacial surgery** When moderate sedation is employed in a dental setting, the dentist anesthesiologist, when simultaneously involved in the conduct of the	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			dental procedure or surgery, must have at least 1 appropriately trained support staff whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. The individual(s) may also be responsible for assisting with interruptible patient-related tasks of short duration. The identity of each dental team member present throughout the administration of minimal and moderate sedation is documented. The team should consist of the surgeon who must be trained and currently competent in ACLS and one additional person trained in BLS for Healthcare Providers who monitors the patient's level of sedation. The individual assigned to monitor the patient may only assist with minor, interruptible tasks within the procedure room once the patient's level of sedation/analgesia and vital signs have stabilized. **Evaluating Compliance:** • Interview staff. • Observe practice. **American Society of Dentist Anesthesiologists: Parameters of Care, 2018** https://pmc.ncbi.nlm.nih.gov/articles/PMC6148692/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Guidelines for the Use of Sedation and General Anesthesia by Dentists, 2016 https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/ada_sedation_use_guidelines.pdf?rev=313932b4f5eb49e491926d4feac00a14&hash=C7C55D7182C639197569D4ED8EDCDDF6 **Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities (AAOMS ParCare 2023)** https://aaoms.org/wp-content/uploads/2024/08/parcare_anesthesia_in-outpatient.pdf	
11-D-9	All anesthetics other than topical or local anesthetic agents are delivered by either an anesthesiologist, or by a CRNA (under physician supervision if required by state or federal law or by a policy adopted by the facility), or by an anesthesiology assistant certified by the NCCAA (under direct supervision of an anesthesiologist). Parenteral sedation, other than propofol, may be administered by a registered nurse under the supervision of a qualified physician.	416.42(b)(1) Standard 416.42(b)(2) Standard B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-D-10	An ASC may be exempted from the requirement for physician supervision of CRNAs as described in QUAD A Standard 11-D-9, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt out is consistent with State law.	416.42(c) Standard 416.42(c)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-D-11	The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time and are effective upon submission.	416.42(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: Facility Staffing				
11-E-1	When a patient is present in the facility to undergo a procedure under a higher level of anesthesia than meets the QUAD A definition of Class A, there is a licensed registered nurse, physician other than the operating surgeon, or physician's assistant designated as the person responsible for patient care in all areas of the facility (i.e. operating room, operating suite, and all patient care areas), in accordance with state/local law.	B C	**Interpretive Guidance:** Licensed practical nurses and medical assistants do not meet this requirement. Both require supervision by a physician or RN. **Evaluating Compliance:** • Interview staff. • Review staffing patterns. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-E-2	All operating suite personnel must meet acceptable standards as defined by their state scope of practice and professional governing bodies, where applicable.	B C	**Interpretive Guidance:** The intent is to ensure that staff follow acceptable standards of practice consistent with state scope of practice laws. Facilities must be knowledgeable about state scope of practice laws for all clinical staff, both direct employees and contract staff and ensure that personnel are not practicing outside of their scope of practice and training. **Evaluating Compliance:** • Interview staff. • Review personnel files and job descriptions. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-E-3	Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever a patient is in the ambulatory surgery facility.	416.44(e) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION F: Nurse Staffing				
11-F-1	The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.	416.46 Condition A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-F-3	Patient care responsibilities must be delineated for all nursing service personnel.	416.46(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-F-4	No nurse provides coverage in the ASC and in an adjacent clinic (or hospital) at the same time.	A B C	**Interpretive Guidance:** The intent is to ensure that nurses provide coverage in the ASC and are not responsible for services provided outside the ASC. **Evaluating Compliance:** • Interview staff. • Observe practice	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-F-5	Nursing services must be provided in accordance with recognized standards of practice.	416.46(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-F-6	There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.	416.46(a) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION G: Post-Anesthesia Care unit (PACU) Staffing				
11-G-1	There is a written policy that whenever parenteral sedation, dissociative drugs, epidural, spinal or general anesthesia is administered, a physician is immediately available until the patient is discharged from the PACU.	B C	**Interpretive Guidance:** The intent is to ensure patient safety until discharged from the PACU when these types of anesthesia are used. Immediately available means that a physician is available and accessible within the facility to provide patient care and respond to emergencies without any delay. **Evaluating Compliance:** • Review policies and procedures. • Interview staff. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-G-2	All recovering patients must be observed and supervised by trained medical personnel in the PACU. A physician, CRNA, PA, or RN currently licensed and certified in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS), as appropriate, is immediately available until the patient has met PACU discharge criteria for discharge from the facility. Local mandates and stricter standards may apply.	B C	**Interpretive Guidance:** The intent is to ensure the safe recovery of patients in the PACU. Medical assistants are not qualified to recover patients. Direct supervision by a physician, CRNA, RN, NP, or PA is required. The physician, CRNA, RN, NP, or PA responsible for recovering the patient is responsible for all PACU documentation. If a contract anesthesiologist brings emergency medications or equipment into the facility and removes them when leaving, the contract	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			anesthesiologist must remain in the facility until all patients have been discharged from the PACU. Direct supervision means being physically present or within an immediate distance and available to respond quickly to a patient's needs. Documentation of BLS certification is not required if ACLS certification is documented. **Evaluating Compliance:** • Interview staff. • Review personnel files. • Review clinical records. • Observe practice **US Legal Direct Supervision Law and Legal Definition** https://definitions.uslegal.com/d/direct-supervision/	

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-G-5	A minimum of one ACLS, and when appropriate PALS as well, certified staff member must be present in the facility until all patients recovering from anesthesia have met the facility's discharge criteria for discharge from the facility.	A B C	**Interpretive Guidance:** The intent is to ensure that all recovering patients are observed and monitored until discharge criteria have been met as determined by discharge criteria and by qualified personnel. If a contract anesthesiologist brings any emergency medications or equipment into the facility and removes any of these items when leaving the facility, the contract anesthesiologist must remain in the facility until all patients have been discharged from the PACU. Documentation of BLS certification is not required if ACLS or PALS certification is documented. **Evaluating Compliance:** • Interview staff. • Review personnel files. • Review staffing patterns. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION H: Personnel Records				
11-H-2	The facility maintains a manual outlining personnel policies that is reviewed annually and updated as needed.	A B C	**Interpretive Guidance:** The intent is to ensure that staff are aware of personnel policies. Having clearly defined policies in place helps ensure that all employees are aware of what is expected from them and how they must behave within the workplace environment. This includes things like dress code, attendance requirements, vacation time allotment, acceptable use of technology, etc. Ensuring these policies are clearly expressed is essential to ensure they can be followed without any misunderstandings. **Evaluating Compliance:** • Review personnel policy manual. • Interview staff.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-H-3	The manual contains personnel policies and records which are maintained according to the Occupational Safety and Health Administration (OSHA), Health Insurance Portability & Accountability Act (HIPAA), and Americans with Disabilities Act (ADA) guidelines. IMPORTANT: Employee information must remain strictly confidential.	A B C	**Interpretive Guidance:** The intent is to ensure that personnel policies and records are maintained appropriately. **Evaluating Compliance:** • Review personnel policy manual. • Interview staff. **OSHA**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1020 **Health Information Privacy** https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html **ADA Title 42 Section 12101 Equal Opportunity for Individuals with Disabilities** https://www.ada.gov/law-and-regs/ada/	
11-H-4	The facility maintains a personnel file for all clinical and administrative employees, including direct and contract employees.	A B C	**Interpretive Guidance:** The intent is to ensure that the facility maintains a personnel file for **all** direct **and** contract clinical and administrative employees. This includes surgeons, anesthesiologists, RNs, LPNs, medical assistants, scrub techs, sterile processing techs, lab and x-ray techs, other clinical employees, and administrative staff. It does not include consultants. **IMPORTANT:** Employee information such as previous employment, health information (except specific to QUAD A standards and state required immunizations or tests) disabilities, employment, and performance reviews are protected and of no interest to the QUAD A surveyor. However, the surveyor does need to confirm that an adequate file is kept on each employee related to the items	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			listed below. The facility has this data available for each employee, including direct and contract employees, separate from the employee files. **Evaluating Compliance:** • Review personnel files.	
11-H-5	Each personnel record contains any health problems of the individual which may be hazardous to the employee, other employees or patients, and a plan of action or special precautions delineated as needed. To be reviewed and updated annually.	A B C	**Interpretive Guidance:** The facility has a policy and procedure that requires staff to inform their employer of any health conditions that may potentially put other staff or patients at risk. This process is in accordance with ADA requirements in terms of when such information can be solicited. Information cannot be obtained until after an offer of employment has been made. However, a facility may make pre-employment inquiries into an applicant's ability to perform job-related functions. If no hazardous health problems exist, this should be documented in the personnel file. There must be documentation present that this information is reviewed and updated on an annual basis and as needed. **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			ADA Title 42 Section 12101 Equal Opportunity for Individuals with Disabilities https://www.ada.gov/law-and-regs/ada/ (Refer to Section 12112(d) Medical Examinations and Inquiries).	
11-H-6	Each personnel record contains resume of training and experience.	A B C	**Interpretive Guidance:** The intent is to ensure that personnel policies files demonstrate that staff are credentialed and competent to perform their duties. The personnel file must also include evidence of any specialized training (i.e. administering moderate sedation). **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-H-7	Each personnel record contains current certification or license if required by the state.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-H-8	Each personnel record contains description of duties.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-H-9	Each personnel record contains a description of duties.	A B C	**Interpretive Guidance:** Physician privileging documents constitute a physician job description. The physician's job description should also include non-patient care duties such as peer review, medical director, facility director, and participation in the development of facility policies and procedures, and the facility's infection control and QAPI programs, etc. **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-H-10	Each personnel record contains on-going records of inoculations or refusals in accordance with State law requirements.	A B C	**Interpretive Guidance:** Vaccination requirements vary from state to state. Confirm the requirements for the state where the facility is located and what their acceptable documentation for proof of vaccination is (i.e. declination, documented vaccine administration, vaccine registry documentation, titer level etc.). The stricter requirement prevails. **Evaluating Compliance:** • Review facility policies and procedures.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			• Review personnel files for evidence of vaccination administration or refusal. **Healthcare Personnel Vaccination Recommendations** www.immunize.org/wp-content/uploads/catg.d/p2017.pdf **OSHA Hepatitis B Vaccination Protection** https://www.osha.gov/publications/bbfact05 **OSHA Hepatitis B Declination (Mandatory)** www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030AppA **Hepatitis B Vaccination: Information for Healthcare Providers** https://www.cdc.gov/vaccines/vpd/hepb/hcp/	
SUB-SECTION I: Personnel Training				
11-I-1	Each personnel record has evidence of annual hazard safety training.	A B C	**Interpretive Guidance:** Hazard identification training ensures that every employee understands the hazards they are likely to encounter in the course of their job, and how to identify each one. Control training ensures that they know what to do when they encounter each hazard (biological, chemical, physical, safety, psychosocial). Online training courses approved by the facility are acceptable. Online courses are reviewed for	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			appropriateness and approved by the facility at least annually. If online training is approved by the facility, it is necessary for the facility to provide additional training regarding action to be taken in the event of exposure specific to their facility. General online training is not acceptable. The hazard safety training is facility specific. Online training using a learning management system (LMS) is acceptable. **Evaluating Compliance:** • Review personnel files	
11-I-2	Each personnel record has evidence of annual blood borne pathogen training.	A B C	**Interpretive Guidance:** Exposure to blood borne pathogens is a risk to the employee's health. Bloodborne pathogen training ensures that every clinical staff member can identify risks of exposure, prevent exposure by taking proper precautions, and take effective action in the event of exposure. This standard does not apply to administrative staff. Training may be in person or online. Online training courses approved by the facility are acceptable. The facility reviews	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			these courses for appropriateness and approves them at least annually. If online training is approved by the facility, it is necessary for the facility to provide additional training regarding action to be taken in the event of exposure specific to their facility. **Evaluating Compliance:** • Review personnel files.	
11-I-3	Each personnel record has evidence of annual universal precaution training.	A B C	**Interpretive Guidance:** This standard does not apply to administrative staff. Training may be in person or online. Online training courses approved by the facility are acceptable. The facility reviews these courses for appropriateness and approves them at least annually. **Evaluating Compliance:** • Review personnel files	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
11-I-4	Each personnel record has evidence of other annual safety training including operative fire safety training and structure fire safety, including operation of a fire extinguisher.	A B C	**Interpretive Guidance:** This training must be facility specific. Online training is not sufficient. **Evaluating Compliance:** • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-I-5	Each personnel record has evidence of at least Basic Cardiopulmonary Life Support (BLS) certification, but preferably Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) for each operating room and PACU team member, depending on the patient population served.	A B C	**Interpretive Guidance:** The intent of this standard is that each clinical staff member, including physicians/surgeons, be minimally certified in BLS with evidence of this in their personnel file. This standard does not apply to administrative staff. The certification training completed is intended for healthcare professionals. Training courses for lay people are not acceptable. Acceptable training includes didactics (may be completed online) and a hands-on skills session. Not all training courses include a hands-on session. Initial and subsequent ACLS certification is obtained from the American Heart Association or another vendor that includes hands-on training and skills demonstration of airway management and automated external defibrillator (AED) use.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
			Evaluating Compliance: • Interview staff. • Clarify which staff are required to have ACLS and/or PALS certification. • Review personnel files	
11-I-6	Clinical personnel must have the knowledge to provide treatment cardiopulmonary and anaphylactic emergencies. At least one member of the operating room team, preferably the physician, pediatric dentist, or anesthesia professional, holds current PALS certification and/or ACLS certification, if appropriate.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** • Interview staff. • Review personnel files. • Observe practice.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
11-I-10	The operating room personnel are familiar with the equipment and procedures utilized in treating emergencies, as discussed in standards section 5-C: Emergency Protocols.	A B C	**Interpretive Guidance:** The intent is to ensure clinical staff can safely use equipment and implement procedures used in the treatment of emergencies. **Evaluating Compliance:** • Review drills performed in the facility. • Interview staff. • Review personnel files.	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

SECTION 12: State Supplements

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: ASC - Florida				
	If the facility is not located in Florida, please select N/A for section 12-A.		**Interpretive Guidance:** **Evaluating Compliance:**	☐ N/A – Facility is not located in Florida
12-A-1	The facility has processes that report and investigate safety incidents, complaints, adverse events and near misses for patients and staff on a defined basis. The results of these investigations of adverse events are reported in the Quality Improvement/Quality Assessment meetings. .	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-2	Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements: Electrical equipment in anesthetizing areas shall be on an audiovisual line isolation monitor, with the exception of radiologic equipment and fixed lighting more than 5 feet above the floor.	C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-3	Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements: Each anesthetic gas machine shall have pin-index system or equivalent safety system and a minimum oxygen flow safety device.	C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-4	The process for entry or admission to the facility for a procedure must be coordinated and defined in a policy.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-5	The facility has a written quality improvement program implemented which should include surveys of projects that Include documentation of quarterly infection control and risk management meetings for the prior 3 years, which should be available for the surveyor.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-6	Smoking Regulations Smoking regulations shall be adopted and shall include not less than the following provisions: (1) Smoking shall be prohibited in any room, ward, or compartment where flammable liquids, combustible gases, or oxygen is used or stored and in any other hazardous location, and such area shall be posted with signs that read NO SMOKING or shall be posted with the international symbol for no smoking. (2) In health care occupancies where smoking is prohibited and signs are prominently placed at all major entrances, secondary signs with language that prohibits smoking shall not be required.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-7	As part of an ongoing risk management program, the facility must conduct a risk assessment of its operational activities at least annually. The assessment should study the risks presented to patients and staff by medication management, fall hazards, infection control, equipment safety, patient risk resulting from long term conditions, and nutrition if any food or beverage services are available to patients. The results of the Risk Assessment should be prioritized for risk mitigation, risk management, and QA/PI projects.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-8	The facility must develop and maintain a program of risk management, appropriate to the organization. This may be carried out in conjunction with the Quality Assessment/Quality Improvement program.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-9	All staff must be educated in risk management activities on commencement of employment and annually thereafter, and when there is an identified need.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-10	The governing body of the organization is responsible for overseeing the program of risk management.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-11	The facility will designate a person or committee responsible for implementation and ongoing management of the risk management program.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-12	The individual responsible for the risk management program shall have free access to all medical records of the licensed facility.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-13	The internal risk manager of each licensed facility shall: Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-14	The internal risk manager of each licensed facility shall: Report to the Department of Health every allegation of sexual misconduct, as defined by state law, and the respective practice act, by a licensed health care practitioner that involves a patient.	A C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-15	Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall: Notify the local police.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-16	The risk manager shall be responsible for the regular and systematic reviewing of all incident reports for the purpose of identifying trends or patterns as to time, place or persons. Upon emergence of any trend or pattern in incident occurrence, the risk manager shall develop recommendations for corrective actions and risk management prevention education and training. Summary data shall be maintained for 3 years.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-17	Adverse events must be tracked and trended on a defined basis.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.
12-A-18	State agencies and QUAD A shall have access to all facility records necessary to carry out the provisions of this manual. Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the state or QUAD A upon request during normal working hours.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
12-A-19	The facility's policies and services are developed with the advice of a group of professional personnel that includes one or more physicians / dentists, one or more physician assistants / nurse practitioners / mid-level clinical personnel, and at least one community member that is not a member of the clinic staff.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient ☐Not Applicable Enter observations of non-compliance, comments or notes here.

SECTION 13: Life Safety Code

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Life Safety Code				
13-A-1	The operating room and recovery room have an emergency power source—such as a generator or battery-powered inverter—with capacity to operate adequate monitoring, anesthesia, surgical equipment, cautery, and lighting for a minimum of 2 hours. If 2 or more operation and recovery rooms are used simultaneously, an adequate emergency power source must be available for each room.).	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
13-A-2	Sufficient electrical outlets are available, labeled and properly grounded to suit the location (e.g. wet locations, cystoscopy-arthroscopy) and connected to emergency power supplies.	A B C	**Interpretive Guidance:** **Evaluating Compliance:** .	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-3	All flammable and combustible materials and supplies are stored and handled in a safe manner with appropriate ventilation according to the most stringent requirement from among the LSC and HCFC requirements, State or local authorities.	A B C	**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-4	Except as otherwise provided in section 42 CFR 416.44, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).	416.44(b)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
13-A-5	Except as otherwise provided in section 42 CFR 416.44, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).	416.44(b)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-5	In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.		**Interpretive Guidance:** **Evaluating Compliance:**	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-6	The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.	416.44(b)(3) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
13-A-7	When a sprinkler system is shut down for more than 10 hours, the ASC must: i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or ii) Establish a fire watch until the system is back in service.	416.44(b)(5) Standard 416.44(b)(5)(i) Standard 416.44(b)(5)(ii) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-8	An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.	416.44(b)(4) Standard A C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-9	Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.	416.44(b)(6) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref/Class	Interpretive Guidance	Score/Findings/Comments
13-A-10	Except as otherwise provided in section 42 CFR 416.44, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).	416.44(b)(6) Standard A C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-11	Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.	416.44(c)(1) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.
13-A-12	If application of the Health Care Facilities Code required under QUAD A 13-A-10 would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.	416.44(c)(2) Standard A B C	**Interpretive Guidance:** **Evaluating Compliance:** **CMS standards Interpretive Guidance can be found at:** SOM (cms.gov) Appendix L	☐Compliant ☐Deficient Enter observations of non-compliance, comments or notes here.

GLOSSARY

Adequate is meant to encompass size, space, maintenance, cleanliness, free of clutter, lighting, appropriately equipped, etc.

Ambulatory surgical center or ASC: any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2. ***[42 CFR 416.2]***

ASC services: means for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures. ***[42 CFR 416.2]***

Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. ***[42 CFR 416.2]***

Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. ***[42 CFR 416.2]***

Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in§416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure. ***[42 CFR 416.2]***

Clinical Personnel refers to the entire surgical/procedural clinical team, including, but not limited to, all surgeons/proceduralists, anesthesia providers, nurses, scrub techs, etc. Employment status (owner, employee, contractor, etc) is not a factor in defining who is included as Clinical Personnel.

Continual is defined as “repeated regularly and frequently in steady, rapid succession,” whereas continuous means “prolonged without interruption at any time.”

GENERAL GLOSSARY

Adequate: Satisfactory or acceptable in quality or quantity, encompassing size, space, maintenance, cleanliness, freedom from clutter, lighting, equipment, and supplies, etc.; it is meant to satisfy a requirement.

Advanced Cardiac Life Support (ACLS): A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in adults that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC).* The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

*** **Advanced practice registered nurses (APRNs**): Licensed registered nurses educated at a master's or doctoral level and in a specific role and patient population. APRNs are prepared with specialized education and certification to assess, diagnose, and manage medical issues. They can also order tests and prescribe medications. APRNs include:

1) Certified registered nurse anesthetist (CRNA).
2) Certified nurse practitioner (CNP).
3) Clinical nurse specialist (CNS).
4) Certified nurse midwife (CNM).

Adverse event: An incident in health care that causes unintended harm to patients or providers and is often preventable. Common adverse events include but are not limited to, medication errors, surgical mistakes, infections acquired in healthcare settings, falls, pressure ulcers, and communication failures. All adverse events that occur within 30 (thirty) days of the procedure must be reported to QUAD A contemporaneously when the facility learns of the event.

Air Exchanges Per Hour (ACH): The number of times that the total air volume in a room or space is completely removed and replaced in an hour.

Ambulatory Health Care vs Business Occupancy https://cdn.ymaws.com/nehes.site-ym.com/resource/resmgr/presentations/2018/doc_presentation_cable081718.pdf

***** Ambulatory surgical center (ASC): Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2. *[42 CFR 416.2]***

Ambulatory Services: for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures. *[42 CFR 416.2]*

Anesthesia professional: A physician anesthesiologist, Certified Registered Nurse anesthetist (CRNA), Certified Anesthesiologist Assistant (CAA), and an appropriately credentialed Oral and Maxillofacial Surgeon.

**** Antisepsis:** The application of an antimicrobial chemical to the skin or mucous membrane to reduce the microbial population.

**** Antiseptic:** An agent used for antisepsis (to kill microorganisms or substantially inhibit their growth).

**** Autoclave:** A common term applied to the performance of steam sterilization under pressure, where bacteria are killed (including spores).

***** Appropriate/appropriately** means especially suitable or compatible; or fitting.

Examples:

- Administrative and patient care areas must have lighting to see all tasks fully.
- Laryngoscopes are cleaned according to the manufacturer's recommendations, though sterilization is preferred.
- Oxygen delivery should be tailored to the appropriate delivery method based on patient need and type/location of the procedure.

Auxiliary Staff: Unlicensed staff who are not state-certified/licensed to independently evaluate patient physical status and cannot legally provide emergency duties beyond Basic Life Support for Healthcare Providers. Auxiliary staff includes dental assistants, registered/certified dental assistants, dental anesthesia/sedation assistants, medical assistants, surgical technicians, and other non-independently Licensed Providers.

Basic Life Support (BLS): A course that trains and certifies participants to promptly recognize several life-threatening emergencies, give high-quality chest compressions, deliver appropriate ventilations, and provide early use of an automatic external defibrillator (AED) through both didactic and hands-on skills return demonstration sessions. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)* and is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

**** Biological Indicator (BI):** A sterilization process monitoring device commercially prepared with a known population of highly resistant spores that tests the effectiveness of the sterilization method being used. The indicator is used to demonstrate that the conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.

Business Associate Agreement (BAA): A contract between the facility and an external business or individual that performs certain functions or activities on behalf of, or provides a service to, the facility when the function, activity, or service involves the creation, receipt, maintenance, or transmission of Protected Health Information (PHI) by the business or individual. The agreement establishes the permissible uses and disclosures of PHI by the business associate, how the business associate will support patients' Privacy Rule rights, and the responsibilities of both parties to maintain the privacy and security of PHI. The Health Insurance Portability and Accountability Act (HIPAA) Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information.

***** Certified Anesthesiologist Assistant (CAA):** A master's degree level non-physician anesthesia care provider that:

1) Is certified by the National Commission for Certification of Anesthesiologist Assistants (NCAA) Note: not a CMS requirement
2) Works under the direction of an anesthesiologist.
3) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and
4) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—
   a) Is accredited by the Committee on Allied Health Education and Accreditation; and
   b) Includes approximately two (2) years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

***** Certified Registered Nurse Anesthetist (CRNA):** An advanced practice registered nurse (APRN) who administers anesthesia and other medications. Physician Supervision (either the operating practitioner or of an anesthesiologist who is immediately available if needed) is required if required by state or federal law.

1) Is licensed as a registered professional nurse by the State in which the nurse practices.

2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists.

3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

4) Meets the following criteria:

   (I) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

   (ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(I) of this definition.

5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

**** Chemical Indicator (CI):** A sterilization monitoring device used to monitor the attainment of one (1) or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.

*****Clinic: A facility (Rural Health Clinic (RHC)) that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:**

- **The medical services are furnished by a group of three or more physicians practicing medicine together.**

- **A physician is present during all hours of the operation of the clinic to furnish medical services, as distinguished from purely administrative services. *[485.703 Condition]***

*****Clinic Administrator: The individual responsible for the internal operation of the RHC in accordance with written policies. A qualified Clinic Administrator is designated by the facility's governing body. *[CMS §485.705(c)(1) and §485.709(b)]***

***** Clinical Personnel: The entire clinical team providing services in the facility, including, but not limited to, all physicians/surgeons/proceduralists, anesthesia providers, nurses, scrub techs, physician assistants, physical/occupational/speech therapists and assistants, social workers, clinical psychologists, marriage and family therapists, mental health counselors, medical assistants, etc. Employment status (owner, employee, contractor, contracted, indirect employee, prn staff, etc.) is not a factor in defining who is included as Clinical Personnel.**

***** Covered ancillary services: items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. *[42 CFR 416.2]***

***** Covered surgical procedures: surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. *[42 CFR 416.2]***

**** Contact Time: "Wet time," also known as "contact time" or "dwell time," is the amount of time a disinfectant or antiseptic solution must remain wet and in direct contact with a target microorganism or on a surface to be effective. This time can range from 15 seconds to 10 minutes, which is the maximum time allowed by the US Environmental Protection Agency (EPA). The contact time is established by the product manufacturer.**

**** Contamination:** The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.

Contemporaneously: Originating, existing, or happening during the same period of time.

Continual: Repeated regularly and frequently in steady, rapid succession.

Continuous: Prolonged without interruption at any time.

Contract & Indirect Employees: These employees are not on the company's payroll and are not restricted by employment laws that apply to direct employees. Work

details are defined in a contract agreed upon by the company and a contractor or third-party agency.

*** 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.

Decontamination: Any physical or chemical process that reduces the number of microorganisms on any inanimate object to render that object safe for subsequent handling.

Dental Anesthesiologist: A licensed DDS or DMD with specialized, hospital-based training in areas including pharmacology, internal medicine, emergency medicine, and pediatric and adult anesthesiology.

Dental Assistant: A dental team member who supports a dental operator in providing more efficient dental treatment. A dental assistant must graduate from an accredited dental assisting training program and earn certification or licensure as State law requires.

Direct Employee: A full- or part-time employee hired by a facility and paid directly through the facility's payroll. They are considered permanent employees because the intention is to work with them long-term rather than temporarily or as needed.

*****Direct Services** means services provided by the clinic's staff. **[42 CFR 491.2]**

**** Disinfectant:** A chemical agent used to kill viruses and bacteria on surfaces. It must be an EPA-registered disinfectant with bactericidal, tuberculocidal, and virucidal properties with specific claims and instructions for HIV and HBV.

**** EPA-Registered:** An EPA registration number signifies that a disinfectant and its claims have been reviewed and approved by the United States Environmental Protection Agency.

*****Extension Location:** A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency. ***[485.703 Condition]***

Facility Director: An individual that manages all aspects of a facility's operations. Their duties include budget management, facility planning, and building system maintenance.

Facility Leadership and Governing Body: These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

Facility Safety Manual: A compilation of safety procedures and guidelines to follow in emergencies or unsafe situations.

***** Facility services: for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure.** ***[42 CFR 416.2]***

General Anesthesia: A drug-induced loss of 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.

Governing Body and Facility Leadership: These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

**** Healthcare-Associated Infection (HAI):** An infection acquired by patients while they are receiving medical care, with confirmation of diagnosis by clinical or laboratory evidence. Infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the healthcare setting.

**** Immediate Use Steam Sterilization (IUSS):** An abbreviated process of steam sterilization of patient care instruments (or devices) for immediate use.

Immediately Available: Accessible (clinician and equipment) without any delay or waiting period. Examples include the physical presence of the health care professional in the facility to assess, evaluate, and provide care to a patient; a supervising physician is physically accessible and able to attend to the patient, without any delay, to address any situation requiring a supervising physician's services; and, 1) dedicated to the facility when on duty, 2) unencumbered by conflicting duties or responsibilities, 3) responding without delay when notified.

****Infection:** The invasion and multiplication of microorganisms in body tissues that cause cellular injury and clinical symptoms.

Intraoperatively: The intraoperative phase extends from the time the patient is admitted to the operating room to the time of anesthesia administration, the performance of the surgical procedure, and until the client is transported to the recovery room or post-anesthesia care unit (PACU).

**** Instructions for Use (IFUs):** Specific, detailed instructions provided by the manufacturer. IFUs for medical devices detail the steps required for cleaning, disinfection, and sterilization that are compatible with that device. Products approved for use in cleaning, disinfection, and sterilization will have specific IFUs to follow (e.g., dilution ratio and contact time) to ensure the product's efficacy.

Legally Qualified: Being in compliance or accordance with specific requirements or conditions. Is qualified under the applicable local, State or Federal law to hold the position for which he or she holds and has met the qualifications of the position.

Log: A written record of performance, events, or day-to-day activities. It is similar to a register**,** which is a written record containing regular entries of items or details.

Examples:

- On any day that controlled substances are administered, the controlled substance inventory and control record (log/register) must be updated as appropriate to reflect controlled substances administered, received, wasted, and currently stored by two licensed healthcare professionals. *(6-D-2)*
- A written record (log/register) of all operative cases is maintained by the facility. *(8-L-1)*

**** Mechanical (Physical) Indicator: Monitors (embedded into the sterilization equipment) that register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence the sterilization system has met the set parameters (or has not, and there is a need for corrective action).**

Medical Director: The clinician responsible for overall oversight of the facility.

***** Medical Staff:** The organized body of licensed physicians and other healthcare providers who are permitted by law and through credentialing and privileges granted by the facility leadership to provide medical care within the facility The medical staff includes physicians, surgeons, specialists, CRNAs, NPs, PAs, and allied health professionals, as identified in facility policy.

*** Minimal Sedation: A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.**

*** Moderate Sedation/Analgesia ("Conscious Sedation" or "Procedural 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.**

*** Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation; rather, it describes "a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure." Indications for monitored anesthesia care include "the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic).**

National Fire Protection Association (NFPA) Business Occupancies, 2021
https://www.nfpa.org/news-blogs-and-articles/blogs/2021/05/07/occupancy-classifications-and-model-codes

1) **Business Occupancy** is an occupancy used for the transaction of business other than mercantile (engaged in commerce) This includes clinics.

2) **Ambulatory Health Care Occupancies** are occupancies used to provide services or treatment simultaneously to four or more patients that provide, on an outpatient basis, one or more of the following:
    a. Treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others
    b. Anesthesia that renders patients incapable of taking action for self-preservation under emergency conditions without the assistance of others
    c. Emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others

    Examples include Day Surgery, Dentists' Offices, oral surgery with sedation, and Endoscopy Centers.

***** Nurse Practitioner (NP)**: A person who is currently licensed to practice in the State and meets the applicable State requirements governing the qualifications of nurse practitioners. And meets at least one (1) of the following conditions:

1) Is certified as a practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice or

2) Has satisfactorily completed a formal one (1) academic year educational program that:

    i. Prepares registered nurses to perform an expanded role.

    ii. That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.

    iii. Awards a degree, diploma, or certificate to persons who successfully complete the program.

3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role) that does not meet the requirements identified above in paragraph 2, and the Nurse Practitioner has been performing an expanded role in the delivery of care for a total of 12 months during the 18-month period immediately preceding the effective date of the subpart.

Nurses Note: Documentation that provides a record of nursing care provided to a patient, family, or community.

Oral Maxillofacial Surgeon (OFM): A medical doctor who is specifically trained in maxillofacial surgery. Because of the focus on the oral area, typically, maxillofacial surgeons attend dental school for four years after receiving their bachelor's degree.

Patient Safety Data Reporting (PSDR): A form of quality control performed by QUAD A accredited facilities within the outpatient setting. Those participating in the data reporting process create a

system-wide culture of clinical quality and demonstrate the positive results of accreditation. PSDR reporting is required for QUAD A facilities participating in Office-Based Surgical, Office-Based Procedural, Oral Maxillofacial Surgery, Pediatric Dentistry, International Surgical, or Medicare ASC programs. Reporting PSDR data is required quarterly, including physician case review. Results of the physician case reviews are discussed during Peer Review meetings.

Pediatric Advanced Life Support (PALS): A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in children that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC).* The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

Pediatric Dentist: A licensed dentist in the state where the dentist practices and who has satisfactorily completed:

1) Four (4) years of dental school.
2) Two (2) additional years of residency training in dentistry for infants, children, teens, and children with special needs.
3) A minimum of 24 months in an advanced education program accredited by the Commission on Dental Accreditation of the American Dental Association. Such programs "must be designed to provide special knowledge and skills beyond the Doctor of Dental Surgery (DDS) or Doctor of Medicine in Dentistry (DMD) training.
4) A curriculum of an advanced program provides the dentist with the necessary didactic background and clinical experiences to provide comprehensive primary oral health care and the services of a specialist.

**** Peel Pouch:** A sterilization pouch (or peel pack) is a disposable package validated for use in a sterilizer to allow penetration of the sterilant to the items placed inside. After sterilization, peel pouches maintain the sterility of the processed item(s) during storage and until needed for use. Pouches are designated as Class II medical devices and may be self-sealing or heat-sealing. "Double pouching" should only be performed if validated for the specific type of pouch and when the manufacturer's instructions for use provide the method of packaging and the sterilization parameters.

Peer: An individual(s) of the same professional discipline and specialty who possesses sufficient training and experience to render judgment on the clinical circumstances under review.

Peer Review: The task of physicians holding one another to the ethical standards of their profession and maintaining the administration of patient safety and quality of care consistent with optimal standards of practice. The American Medical Association (AMA) publishes information regarding the peer review process and describes the composition of the Peer Review Committee as follows:

> *Peer review is conducted in good faith* ***by physicians who are within the same geographic area or jurisdiction and medical specialty of the physician subject to review*** *to ensure that all physicians consistently maintain optimal standards of competency to practice medicine. Physicians outside of the organization that are convening peer review may participate in that organization's peer review of a physician if the reviewing physician is within the same geographic area or jurisdiction and medical specialty as the physician who is the subject of peer review.*

What is Peer Review? https://www.amwa-doc.org/what-is-peer-review/

Personnel: Everyone employed (including volunteers) at a facility, including both direct and indirect (contract) employees who provide care, treatment, or services to patients. The terms “personnel” and “staff” are synonymous.

**** Personal Protective Equipment (PPE):** Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury and minimize exposure to hazards.

***** Physician**: Providers who medically diagnose patients, prescribe and manage medication, and supervise other medical staff A licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO) legally authorized to practice medicine or surgery in the State in which the function is performed; and a Doctor of Dental Surgery (DDS) or Doctor of Dental Medicine (DMD) who is legally authorized to practice dentistry by the State in which he/she performs such function and who is acting within the scope of his/her license and a Doctor of Podiatric Medicine

Physician Anesthesiologist: A medical doctor who has attained either a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO) degree and has chosen to specialize in the field of anesthesiology and specializes in anesthesia care, pain management, and critical care medicine, and have the necessary knowledge to understand and treat the entire human body.

***** Physician Assistant (PA):** An individual who meets the applicable State requirements governing the qualifications for assistants to primary care physicians. And meets one of the following conditions:

1) The physician assistant is currently certified by the National Commission on Certification of Physician Assistants to assist physicians.

2) The physician assistant has satisfactorily completed a program for preparing physician's assistants that:

   i. Was at least one (1) academic year in length.

   ii. Consisted of supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

   iii. Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

3) The physician assistant has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

4) Is licensed as a PA by the State in which the PA practices.

Proceduralist: A licensed physician, usually a specialist or subspecialist, trained and qualified to perform diagnostic or therapeutic procedures. A licensed and trained CRNA and PA may also conduct selected procedures based on state law and scope of practice.

Procedural accreditation: This is intended for office-based facilities performing procedures in medical specialties including gastroenterology, urology/nephrology, gynecology, interventional radiology/vascular access, pain management, and dermatology. Procedures are performed by

specialists including Gastroenterologists, Urologists/Nephrologists, Gynecologists, Pain Management Specialists, Dermatologists, or Interventional Radiologists/Vein Specialists, and may include minimally invasive procedures and approved minor surgical procedures (e.g. minor urological surgical procedures including circumcisions, vasectomies; minor dermatological procedures including mole/growth removal, minimally invasive gynecological surgeries as entered through the vagina, etc.).

Progress note: An essential tool used in healthcare to document patient information, medical history, treatment plans, and progress throughout a patient's care. Progress notes are also a crucial communication tool among healthcare professionals, ensuring continuity of care and facilitating collaboration.

Public health agency: an official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services. ***[485.703 Condition]***

Qualified: An individual who is qualified by education, training, licensure/regulation (when applicable, also includes registration and certification), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

Rehabilitation agency -

An agency that:

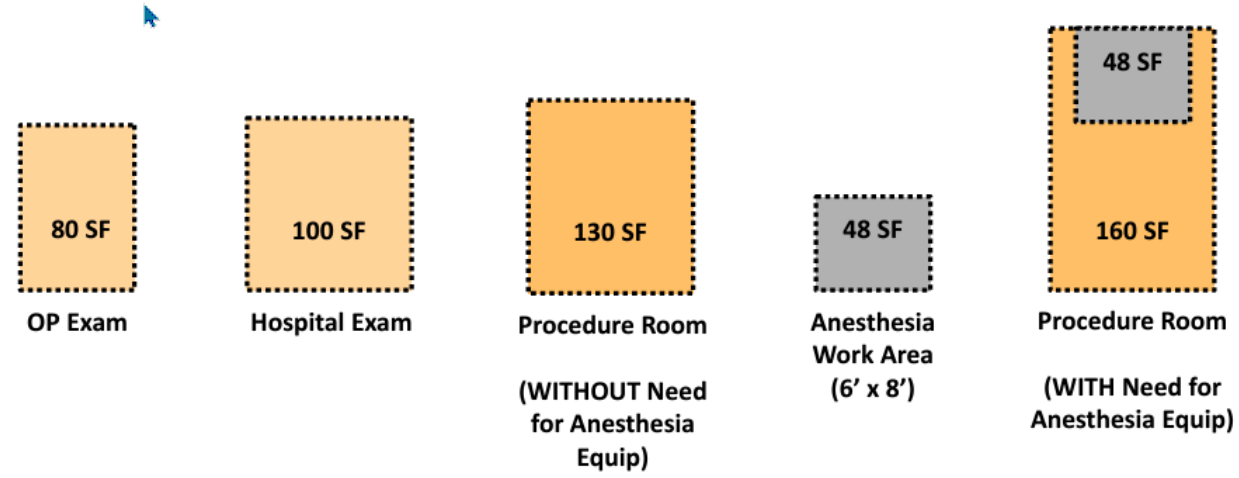
- Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
- Provides at least physical therapy or speech-language pathology services.

[485.703 Condition]

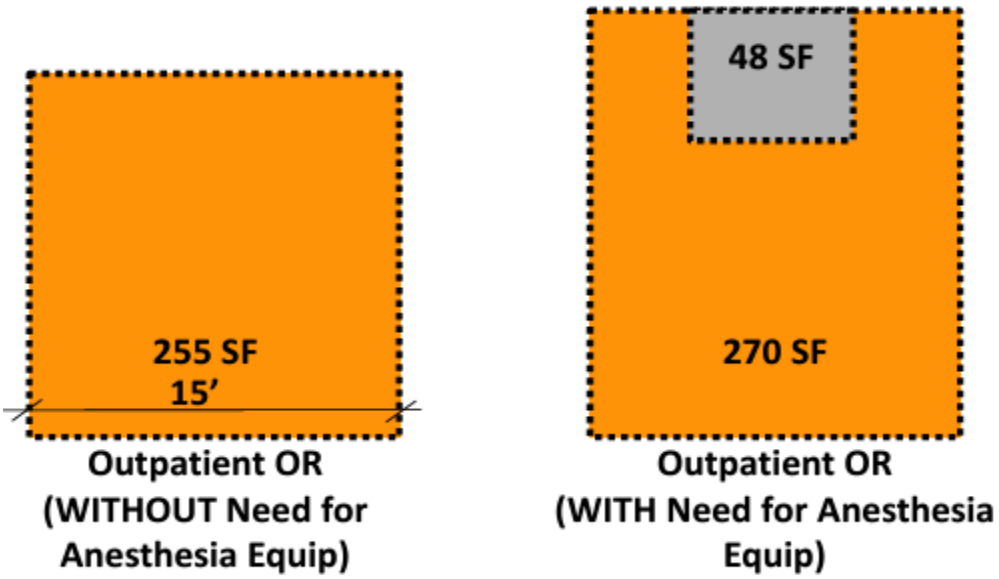
****** Room Classifications:**

Room Type	Use	Environmental Controls		
		Location	Ventilation (excerpted from ASHRAE 170)	Surfaces
Exam Room or **Treatment Room**	Patient care that may require high-level disinfected or sterile instruments **but does not require the environmental controls of a procedure room**	Accessed from an **unrestricted** area	**4 total ACH** for general exam room **6 total ACH** for exam rooms programmed for use by patients with undiagnosed gastrointestinal symptoms, respiratory symptoms, or skin symptoms No pressure requirement Standard diffuser and return array	**Ceilings:** Cleanable with routine housekeeping equipment **Floor:** No special requirement **Walls:** No special requirement
Procedure Room	Patient care that requires high-level disinfection or sterile instruments and some environmental controls **but does not require the environmental controls of an operating room**	Accessed from an **unrestricted** or a semi-restricted area	**15 ACH / Positive pressure** Standard diffuser and return array	**Ceilings:** Smooth and without crevices, scrubbable, non-absorptive, non-perforated; capable of withstanding cleaning chemicals; without crevices; lay-in ceiling permitted if gasketed or each ceiling tile weighs at least one pound per square foot and no perforated, tegular, serrated, or highly textured tiles. Lay-in ceiling permitted if gasketed or each ceiling tile weighs at least 1lb/SF **Floor and wall base assemblies for cystoscopy, urology, and endoscopy procedure rooms:** Monolithic with an integral coved wall base that is carried up the wall a minimum of 6' **Wall finishes for endoscopy:** Free of fissures, open joints, or crevices that may retain or permit passage of dirt particles
Operating Room	**Invasive procedures*** Any procedure during which the patient will require **physiological monitoring and is anticipated to require active life support**	Accessed from a **semi-restricted area**	**20 total ACH / Positive pressure** Primary supply diffuser array extend a minimum of 12' beyond the footprint of the surgical table on each side At least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible	**Ceilings:** Monolithic, scrubbable, capable of withstanding cleaning and/or disinfecting chemicals, gasketed access openings **Floor and wall base assemblies**: Monolithic with an integral coved wall base that is carried up the wall a minimum of 6' **Wall finishes:** Free of fissures, open joints, or crevices that may retain or permit passage of dirt particles

2018 FGI Guidelines for Minimum Room Sizes: Exam, Treatment & Procedure Rooms



2018 FGI Guidelines for Minimum Room Sizes: Operating Rooms



*** **Rural area:** An area that is not delineated as an urbanized area by the Bureau of the Census. **[42 CFR 491.2]**

*** **Rural health clinic:** A clinic located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases and meets all other requirements of this subpart. **[42 CFR 491.2]**

***** Secretary:** The Secretary of Health and Human Services, or any official to whom he/she has delegated pertinent authority.

***** Shortage area:** A defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act). **[42 CFR 491.2]**

Staff: Anyone employed (part-time, full-time) at a facility, including both direct and indirect (contract) employees that provide care, treatment, or services to patients. The terms "personnel" and "staff" are synonymous.

***** Direct Services:** services provided by the clinic's staff. **[42 CFR 491.2]**

**** Sterile:** The state of being free from all living microorganisms. In practice, it is usually described as a probability function (e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000).

**** Sterilization:** A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability (which, even though is a very low number, may never be zero).

Surgeon: A physician trained and qualified to perform surgical procedures.

***** Surgery** is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous when ordered by a physician.) Surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

1) **Major surgery** is an invasive operative procedure where one (1) or more of the following occurs:
    a. A body cavity is entered.
    b. A mesenchymal barrier is crossed.
    c. A fascial plane is opened
    d. An organ is removed
    e. Normal anatomy is operatively altered

2) **Minor Surgery** is an invasive operative procedure in which only skin, mucous membranes, or superficial connective tissue is manipulated.

***** Supervision**

1. **Direct Supervision:** The supervising physician must be immediately available if needed, meaning physically present in the facility, and prepared to immediately conduct hands-on intervention if needed. However, the physician does not need to be in the room throughout the performance of the service.

2. **General supervision:** The service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and maintain the necessary equipment and supplies is the physician's continuing responsibility.

3. **Personal supervision:** A physician must be present in the room during the procedure.

*** Surgical Site Infection (SSI):** An infection at the site of a surgical incision. The SSI may be superficial, deep, or extend to organs. Patients should be monitored for SSIs for thirty (30) days after surgery or procedures or three-hundred and sixty-five (365) days after implant placement.

Ventilation of Health Care Facilities. ASHRAE/ASHE standard 170-2008

TABLE 7-1 Design Parameters

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	RH (k), %	Design Temperature (l), °F/°C
SURGERY AND CRITICAL CARE							
Class B and C operating rooms, (m), (n), (o)	Positive	4	20	N/R	No	2030–60	68–75/20–24
Operating/surgical cystoscopic rooms, (m), (n), (o)	Positive	4	20	N/R	No	2030–60	68–75/20–24
Delivery room (Caesarean) (m), (n), (o)	Positive	4	20	N/R	No	2030–60	68–75/20–24
Treatment room (p)	N/R	2	6	N/R	N/R	2030–60	70–75/21–24
Trauma room (crisis or shock) (c)	Positive	3	15	N/R	No	2030–60	70–75/21–24
Laser eye room	Positive	3	15	N/R	No	2030–60	70–75/21–24
Class A Operating/Procedure room (o), (d)	Positive	3	15	N/R	No	2030–60	70–75/21–24
DIAGNOSTIC AND TREATMENT							
Gastrointestinal endoscopy procedure room	Positive	2	6	N/R	No	2030–60	68–73/20–23

APPENDIX 1 – LSC REFERENCES

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_location.html

If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

NFPA 99, Standards for Health Care Facilities Code of the National

FireProtection Association 99, 2012 edition, issued August 11, 2011.

TIA 12-2 to NFPA 99, issued August 11, 2011.

TIA 12-3 to NFPA 99, issued August 9, 2012.

TIA 12-4 to NFPA 99, issued March 7, 2013. (v)TIA 12-5 to NFPA 99, issued August 1, 2013.

TIA 12-6 to NFPA 99, issued March 3, 2014.

NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

TIA 12-1 to NFPA 101, issued August 11, 2011.

TIA 12-2 to NFPA 101, issued October 30, 2012.

TIA 12-3 to NFPA 101,issued October 22, 2013.

TIA 12-4 to NFPA 101, issued October 22, 2013. [42 CFR 416.44(f)

SPECIAL THANKS & RECOGNITION

QUAD A and its Board of Directors would like to express their gratitude to the team of outstanding professionals who volunteered and contributed their vast knowledge, experience, expertise, and time to ensure that QUAD A is able to attain its mission of improving patient safety worldwide. Their months of extensive work, sacrifice, and collaboration are greatly appreciated.

William Rosenblatt, MD *Plastic Surgery* *President, QUAD A Board of Directors, QUAD A Surveyor*	**Janice Izlar, CRNA, DNAP, CRNA** *Anesthesia* *Standards Committee Chair, QUAD A Board of Directors*
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