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**Medicare Ambulatory Surgical Center (ASC)**

**Standards Manual**

Version 8.2, Effective February 1, 2023

**QUAD A**

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**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 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” is the first standard under Section 2, Sub-section C. Therefore, the unique identifier for this standard is: 2-C-1.

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:**

Click or tap here to enter text.

**SECTION 1: BASIC MANDATES**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: ANESTHESIA OPTIONS** | | | | | |
| **1-A-1** | In this facility, operations may be performed under:  Local Anesthesia, which may be administered by any of the following:  - Surgeon/proceduralist  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-2** | In this facility, operations may be performed under:  Topical Anesthesia, which may be administered by any of the following:  - Surgeon/proceduralist  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-3** | In Class A cases, a single dose of the same post-operative analgesic prescribed to the patient may be administered to that patient pre-operatively. Any additional doses or agents is considered sedation and must be conducted under Class B, C-M, or C standards. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-5** | In this facility, operations may be performed under:  Parenteral Sedation, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-8** | In this facility, operations may be performed under:  Field and Peripheral Nerve Blocks, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-10** | In this facility, operations may be performed under:  Dissociative Drugs, excluding Propofol, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-12** | In this facility, operations may be performed under:  Nitrous Oxide, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist  - Registered nurse under the supervision of a qualified physician |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-14** | 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. |  | B | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-15** | In this facility, operations may be performed under:  Propofol, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-17** | The use of endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited. |  | C-M | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-18** | In this facility, operations may be performed under:  Epidural Anesthesia, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-19** | In this facility, operations may be performed under:  Spinal Anesthesia, which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-20** | In this facility, operations may be performed under:  General Anesthesia (with or without endotracheal intubation or laryngeal mask airway anesthesia), which may be administered by any of the following:  - Anesthesiologist  - Certified Registered Nurse Anesthetist (CRNA) under physician supervision if required by state/local law  - Anesthesia assistant as certified by the National Commission for the Certification of Anesthesiologist Assistants (NCCAA) under direct supervision of an anesthesiologist |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-A-22** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: BASIC MANDATES** | | | | | |
| **1-B-1** | The facility has defined a mission statement that reflects the population it serves and the services it provides. | 416.40 Condition | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-B-2** | Onsite QUAD A surveys typically involve the attention of the Medical Director, the Facility Director, an anesthesia provider, and the facility staff working intensely with the QUAD A surveyor(s). The survey process must remain focused, and therefore, QUAD A has directed that equipment representatives not be present during QUAD A's surveys. Accreditation consultants may be present during the surveys; however, QUAD A asks that consultants remain silent during the survey process until it is completed. All QUAD A surveyor(s) have the authority to request any participants to leave the survey process if interference becomes a problem. QUAD A greatly appreciates the cooperation of all concerned parties by complying with this directive. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | 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 should be referred to alternative facilities. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-C-2** | The facility should have a scheduling policy that includes only those procedures and/or combination of procedures of duration and degree that permit safe recovery and discharge from the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-C-4** | If children are operated upon in the facility, there should be a written policy defining the unique perioperative care of pediatric patients. This is based upon considerations of age, risk categories, surgery, facility equipment, and capability. The written policy for pediatric patients is available and current. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐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  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-D-19** | The patient has a right to receive care in a safe setting. | 416.50(f)(2) Standard | A  B  C-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: QUAD A-MANDATED REPORTING** | | | | | |
| **1-E-1** | Changes in facility ownership must be reported to the QUAD A office within thirty (30) days of the change. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-E-2** | Any change in the physician’s staff must be reported in writing to the QUAD A office within thirty (30) days of such changes. Copies of the credentials of any new staff, including their current medical license, ABMS Board Certification, AOABOS Board Certification or other approved Boards, letter of eligibility or equivalent documentation, and current documentation of hospital privileges or satisfactory explanation for the lack thereof must also be sent to the QUAD A office. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-E-3** | Any action affecting the current professional license of the Medical Director, a member of the medical staff, a member of the physician’s pain management staff or other licensed facility staff must be reported in writing to the QUAD A office within ten (10) days of the time the Facility Director becomes aware of such action. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 a QUAD A-accredited facility, an unannounced survey may be performed by a senior surveyor. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 submission of random cases and all adverse events to the QUAD A portal at [www.quada.org](http://www.quada.org). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-3** | All adverse events which occur within thirty (30) days of any procedure are submitted contemporaneously with the facility learning of the occurrence of such sequelae to the online Patient Safety Data Reporting portal. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-4** | Reportable adverse events include, but are not limited to:  Any unplanned hospital admission |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-5** | Reportable adverse events include, but are not limited to:  Any emergency room visit |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-9** | Reportable adverse events include, but are not limited to:  Any allergic reactions |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-10** | Reportable adverse events include, but are not limited to:  Any incorrect needle or sponge count |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-11** | Reportable adverse events include, but are not limited to:  Any patient or family complaint |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-14** | Each adverse event submission must include:  The identification of the problem |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-15** | Each adverse event submission must include:  The immediate treatment or disposition of the case |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-16** | Each adverse event submission must include:  The outcome |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-17** | Each adverse event submission must include:  The reason for the problem |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **1-F-18** | Each adverse event submission must include:  An assessment of the efficacy of treatment. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 2: FACILITY LAYOUT & ENVIRONMENT**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-A-4** | The operating suite is physically separate from the general office. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-A-5** | An exam room may function as an operating room. |  | A | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-A-6** | There is a room dedicated for use as an operating room. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-A-7** | All major surgery is done in the separate and distinct operating room(s). |  | A  B  C-M  C | ☐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, or facility personnel. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[2-B-2](#ICWorksheetHandHygien" \o "Go Back to Infection Control Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-B-3** | The facility displays a professional appearance in keeping with a medical facility designed to carry out procedures. The facility must be neat, comfortable and clean and should include a waiting area, business office and sanitary lavatory facilities. One or more dedicated exam rooms must be available that provide for privacy and treatment in a sanitary, orderly environment. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-B-4** | The walls and countertops are covered with smooth and easy-to-clean material that is free from tears, breaks, or cracks. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-B-5** | The floors are covered with smooth and easy-to-clean material that is free from breaks, or cracks. If the floors contain seams or individual tiles, they are sealed with an impermeable sealant other than silicone. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-B-6** | All openings to outdoor air are effectively protected against the entrance of insects, animals, etc. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: OPERATING ROOM ENVIRONMENT** | | | | | |
| **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-M  C | ☐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. Facility personnel can physically demonstrate to the inspector that the emergency criteria, as stated above, can be met in the operating room space available. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-C-3** | Each operating room is adequately ventilated and temperature controlled. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-C-4** | Each operating room is properly cleaned, maintained and free of litter and clutter. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-C-5** | There is adequate storage space within the operating room to hold equipment, supplies and medications. Storage space should be adequate to minimize the need to leave the operating room for frequently used supplies, equipment and/or medications. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-C-6** | If a pre-existing sink is present in the operating room, a written policy to prohibit the use of the sink during sterile surgical procedures must be in place. A sink is permissible in an operating room which is exclusively used for endoscopic or urological procedures in accordance with the standards of those professions. Requests for allowance by other specialties will be reviewed on a case -by-case basis. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-C-7** | The operating room ceiling surface or drop-in tiles are smooth, washable, and free of particulate matter that could contaminate the operating room. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION D: POST-ANESTHESIA CARE UNIT (PACU) ENVIRONMENT** | | | | | |
| **2-D-1** | The PACU is maintained, clean and free of litter. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: STORAGE** | | | | | |
| **2-E-1** | Sterile supplies 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **2-E-2** | Storage space provides easy access for identification and inventory of supplies. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 3: SAFETY**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** | |
| --- | --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: General Safety** | | | | | |
| **3-A-1** | QUAD A is committed to establishing minimum guidelines to provide safe and effective outpatient procedure care. 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 stricter regulation (whether it is the QUAD A Standard or local, state, or federal law). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **SUB-SECTION B: Facility Safety Manual** | | | | | |
| **3-B-1** | There is a Facility Safety Manual. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-B-2** | The facility safety manual contains all applicable requirements of OSHA. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-B-3** | The facility safety manual is in accordance with all other federal/national, provincial, state, and local regulations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-B-4** | The facility safety manual provides employees with information about hazardous chemicals used and methods to minimize hazards to personnel. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-B-5** | There is a written exposure control plan, which is reviewed and updated at least annually. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-B-6** | There is a written chemical hazard communication program, which is reviewed and updated annually. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **SUB-SECTION C: Hazardous Agents** | | | | | |
| **3-C-1** | All explosive and combustible materials are stored and handled in a safe manner according to state, local, and/or National Fire Protection Association (NFPA) codes. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-C-5** | Hazardous chemicals are labeled as hazardous. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **SUB-SECTION D: Medical Hazardous Waste** | | | | | |
| **3-D-1** | All medical hazardous wastes are stored in OSHA (Occupational Safety and Health Act) acceptable containers and separated from general refuse for special collection and handling. |  | A  B  C-M  C | ☐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 which are located as close to the use area as is practical. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **SUB-SECTION G: Personnel Safety** | | | | | |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **[3-G-2](#PerWorksheet1)** | Personnel are properly trained in the control procedures and work practices that have been demonstrated to reduce occupational exposures to anesthetic gases. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **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, etc.). |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-H-2** | If x-ray equipment is used, safety measures are taken to protect patients and staff from injury. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-H-3** | Warnings and signage exist to warn those whose health may be affected by x-rays. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-H-4** | Staff maintains dosimetry badges and records, if applicable, for at least three (3) years. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | 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 ASC 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |
| **3-H-6** | If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC 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-M  C | ☐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, include appropriate eyewear, covered mirrors, covered windows, signage on the door, etc. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. | |

**SECTION 4: EQUIPMENT**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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 codes. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Operating Room Equipment** | | | | | |
| **4-B-1** | Only properly inspected equipment is used in the operating suite. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-2** | There is an adequate operating room table or chair. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-3** | The operating room is provided with adequate general lighting in the ceiling. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-4** | Adequate illumination for patients, machines and monitoring equipment, which can include battery powered illuminating systems. |  | B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-6** | Sequential compressive 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-7** | When unipolar electrocautery is used, a single-use/ disposable grounding pad is used. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-B-8** | “Forced air warmers,” blanket warmers, or other devices are used to maintain the patient’s temperature. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Anesthesia Equipment** | | | | | |
| **4-C-1** | The operating room is equipped with an EKG monitor with pulse read-out. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-2** | The operating room is equipped with a pulse oximeter. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-3** | The operating room is equipped with blood pressure monitoring equipment as appropriate for the patient population. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-4** | The operating room is equipped with oral airways for each size of patient treated in the facility. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-5** | The operating room is equipped with nasopharyngeal airways and laryngeal mask airways for each size of patient treated in the facility. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-6** | The operating room is equipped with a laryngoscope, functional. Laryngoscope is cleaned as appropriate, HLD or sterilized. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-7** | The operating room is equipped with a comprehensive assortment of endotracheal tubes to cover full range of patients being treated. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-8** | The operating room is equipped with endotracheal stylet(s). |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-9** | The operating room is equipped with a positive pressure ventilation device (e.g., Ambu® bag, bag valve mask). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-10** | The operating room is equipped with a source of oxygen with appropriate delivery devices (e.g. nasal cannula, face mask). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-11** | The operating room is equipped with a source of adequate and reliable source suction and suction equipment. |  | A  B  C-M  C | ☐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 surgery (back up should consist of at least one full E cylinder). Back up oxygen source should have a regulator on it and be ready to use. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-13** | The operating room is equipped with an inspired gas oxygen monitor on the anesthesia machine. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-C-14** | The operating room is equipped with a carbon dioxide monitor which is used on all sedation and general anesthesia cases. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-D-2** | A separate pulse oximeter is available for each patient in the PACU. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: Maintenance of Equipment** | | | | | |
| **4-E-1** | A biomedical technician annually inspects all equipment (including electrical outlets, breaker/fuse boxes, and emergency light and power supplies) 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 with records kept for a minimum of at least three (3) years. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **4-E-5** | The manufacturer’s specifications and requirements are kept in an organized file and followed for each piece of equipment. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 5: IN CASE OF EMERGENCY**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: Emergency Equipment** | | | | | |
| **5-A-1** | Emergency cart is available with defibrillator or automated external defibrillator (AED), necessary drugs, and other CPR equipment (e.g. suction, pediatric defib pads, current PALS algorithm and/or ACLS algorithm if appropriate). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-A-2** | The current and complete MHAUS malignant hyperthermia algorithm must be available on the emergency cart. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-A-3** | The standard defibrillator, or an Automated External Defibrillator (AED), is checked at least weekly for operability, and the test results are kept for a minimum of three (3) years. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-A-4** | The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. | 416.44(d) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-A-6** | The emergency equipment must be appropriate for the facility's patient population. | 416.44(d)(2) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Emergency Power** | | | | | |
| **5-B-2** | The operating room(s) and recovery room have an emergency power source, (e.g., a generator or battery powered inverter), with capacity to operate adequate lighting, monitoring, anesthesia, and procedure equipment for a minimum of two (2) hours. If two or more operating rooms are used simultaneously, an adequate emergency power source must be available for all operating rooms. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Emergency Protocols** | | | | | |
| **5-C-1** | There must be a written protocol for emergency evacuation of the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-2** | There must be 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. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-3** | There must be a written protocol for fires and fire drills. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-4** | There must be a written protocol for returning patients to the operating room in the event of patient emergencies. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-5** | There must be a written protocol for malignant hyperthermia (MH). |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-6** | There must be a written protocol for cardiopulmonary resuscitation (CPR). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-7** | There must be a written protocol for a situation in which the surgeon becomes incapacitated. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-8** | There must be a written protocol for a situation in which the anesthesiologist or CRNA becomes incapacitated. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-9** | There must be a written protocol for response to power failure emergencies. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-C-10** | There must be a written protocol for transferring patients to a hospital in an emergency. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-14** | Safe evacuation from the Provider/Supplier must include transportation. | 416.54(b)(2)(iii) Standard | A  B  C-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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)(iii) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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)(iv) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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)(ii) Standard | A  B  C-M  C | ☐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)(ii) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| [**5-D-30**](#PerWorksheet) | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[5-D-31](#PerWorksheet" \o "Go Back to Personnel Worksheet)** | The training program must provide emergency preparedness training at least every two (2) years. | 416.54.d.1.ii Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[5-D-32](#PerWorksheet1)** | The training program must maintain documentation of all emergency preparedness training. | 416.54(d)(1)(iii) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[5-D-33](#PerWorksheet" \o "Go Back to Personnel Worksheet)** | The training program must demonstrate staff knowledge of emergency procedures. | 416.54(d)(1)(iv) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[5-D-34](#PerWorksheet1)** | 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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: Emergency Preparedness Plan – Integrated Healthcare Systems** | | | | | |
| **5-E-1** | If a Provider/Supplier is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the Provider/Supplier may choose to participate in the healthcare system's coordinated emergency preparedness program. | 416.54(e) Standard | A  B  C-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 6: MEDICATIONS**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[6-A-2](#ICWorksheet6A2" \o "Return to Infection Control Worksheet)** | Drugs must be prepared and administered according to established policies and acceptable standards of practice. | 416.48(a) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[6-A-3](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Blood and Blood Substitutes** | | | | | |
| **6-C-1** | If blood were to be used, there is a protocol for it to be typed, cross- matched, checked, and verified. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-C-2** | Blood and blood products must be administered only by physicians or registered nurses. | 416.48(a)(2) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION D: Controlled Substances** | | | | | |
| **6-D-1** | All controlled substances are secured and locked under supervised access. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-D-2** | There is a dated controlled substance inventory and a control record which 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, secured computer record consistent with state and federal law. A loose-leaf notebook or a spiral-bound notebook does not fulfill this regulation. This log must be kept in the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-D-3** | The inventory of controlled substances is verified by two (2) licensed members of the operating room team on any day that controlled substances are administered, and in compliance with federal/national, provincial, state, and local regulations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-D-4** | There must be a record of receipt and disposition of all controlled substances. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: ACLS/PALS Algorithm** | | | | | |
| **6-E-1** | A complete copy of the current ACLS and/or PALS Algorithm, as appropriate, must be available on the emergency cart. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-2** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Seizure arresting medication (a benzodiazepine, e.g. Midazolam). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-4** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Adenosine |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-5** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Epinephrine. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-6** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Anti-Hypertensives. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-7** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Lidocaine—plain. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-8** | The following medication must be available in the facility at all times as required by current ACLS algorithm: Atropine. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-9** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Nitroglycerin, sublingual or spray. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-10** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  If narcotics are used in the facility, a narcotic antagonist (eg, Narcan) should be present. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-11** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Bronchospasm-arresting medication (inhaled beta-agonist, eg albuterol). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-E-12** | The following medication must be available in the facility at all times as required by current ACLS algorithm:  Intravenous corticosteroids (eg, dexamethasone). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION F: Emergency Medications** | | | | | |
| **6-F-1** | All emergency medications as noted in the following standards must be available and in the facility at all times. Licensed personnel in the facility must know their location. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-F-2** | The following medication must be available in the facility at all times:  IV Antihistamines (e.g. Diphenhydramine). |  | A  B  C-M  C | ☐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 (e.g. esmolol or labetalol). |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-F-5** | The following medication must be available in the facility at all times:  If Benzodiazepine is used in the facility, a reversing agent must be available (e.g. Mazicon™, Flumazenil). |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION G: Malignant Hyperthermia** | | | | | |
|  | *If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility, the following requirements apply:* |  |  | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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.  In this instance, MH-related components as outlined in standards 6-G-5, 6-G-6, 6-G-7,6-G-8, 6-G-9, and 6-G-10 are **not** required. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[6-G-2](#MedWorksheet)** | There must be adequate screening for MH risk 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-3** | All operating surgeons and anesthesiology providers must be aware of genetic and/or CHCT (Caffeine-Halothane Contracture Testing) for MH and refer patients for appropriate testing if there is a suspicious history as above prior to permitting surgery to take place in the facility. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-4** | All operating surgeons and anesthesia providers must be able to demonstrate familiarity with the early recognition of impending MH crisis as defined by [MHAUS](https://www.mhaus.org/mhau001/assets/File/Recommendations%20with%20Table%20of%20Contents(1).pdf). |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[6-G-5](#PerWorksheet2)** | All staff 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-6** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-7** | A minimum of 4 ampoules, 50cc’s each, of sodium bicarbonate (NaHCO3). |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-8** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-9** | 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 15 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-10** | Flow sheets for any MH intervention as well as forms to rapidly communicate progress of intervention with receiving facilities are on the emergency cart and all facilities must document and report any "adverse metabolic or musculoskeletal reaction to anesthesia". This documentation must be transportable with the patient when transferred to receiving facility. |  | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **6-G-11** | Facilities must have a policy for MH transfer including EMS 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 7: INFECTION CONTROL**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: Infection Control** | | | | | |
| **[7-A-1](#ICWorksheet7A1" \o "Go Back to Infection Control Worksheet)** | The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. | 416.51 Condition | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-A-4** | Scrub suits, caps or hair covers, gloves, operative gowns, masks, eye protection, and all other appropriate personal protective equipment is used for all appropriate procedures. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-A-5** | A sterile field is used during all operations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[7-A-6](#ICWorksheet7A67891" \o "Go Back to Infection Control Worksheet)** | The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. | 416.51(b) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[7-A-7](#ICWorksheet7A67891" \o "Go Back to Infection Control Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[7-A-8](#ICWorksheet7A67891" \o "Go Back to Infection Control Worksheet)** | The Infection Control program is an integral part of the ASC’s quality assessment and performance improvement program. | 416.51(b)(2) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[7-A-9](#ICWorksheet7A67891" \o "Go Back to Infection Control Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-A-10** | The infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-A-11** | Appropriate scrub facilities are provided for the operating room staff consistent with current CDC guidelines for hand hygiene and surgical scrub. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Hand Hygiene** | | | | | |
| **7-B-1** | Surgical scrub, soap, and/or alcohol cleansers are provided for the operating room staff consistent with current [CDC](https://www.cdc.gov/handhygiene/providers/guideline.html) and [WHO](https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf;jsessionid=D85D192EC34E6F1D94430D8F632FE741?sequence=1) guidelines for hand hygiene. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Instrument Processing** | | | | | |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-C-3** | The instrument preparation and assembly area (clean utility area) is separated by walls or space from the instrument cleaning area (dirty utility area) or, there is a policy to clean and disinfect the dirty utility area before preparing and assembling packs for sterilization. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-C-4** | If one sink is used both for dirty instruments and to hand/arm scrub for procedures, there is a written policy to clean and disinfect the sink prior to hand/arm scrubbing. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION D: Sterilization** | | | | | |
| **7-D-1** | All instruments used in patient care are sterilized, where applicable. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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.  All soiled instruments are to be treated with an enzymatic cleaner if not processed immediately for sterilization. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-3** | Additional methods in use can be chemical autoclave (Chemclave©) or gas (ethylene oxide/EO) sterilizer. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-4** | Gas sterilizers and automated endoscope re-processors (AER) must be vented as per manufacturer’s specifications. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-5** | Each load in the autoclave is checked with indicator tape, chemical monitors, or other effective means both on the outside and inside of the pack. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-6** | Sterile supplies are labeled to indicate sterility; packaged and sealed with autoclave tape to prevent accidental opening. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-7** | Each sterilized pack is marked with the date of sterilization and, when applicable, with the expiration date. When more than one autoclave is available, each pack must additionally be labeled to identify in which autoclave it was sterilized. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-8** | A weekly spore test, or its equivalent, is performed on each autoclave and the results filed and kept for three (3) years. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-9** | There is a protocol for corrective action if a spore test is positive. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-D-10** | Monitoring records 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: High-Level Disinfection (HLD)** | | | | | |
| **7-E-1** | High-level disinfection is used only for non-autoclavable endoscopic equipment, and in areas that are categorized as semi-critical where contact will be made with mucus membrane or other body surfaces that are not sterile. The manufacturer’s recommendations for usage should be followed at all times. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-E-2** | Endoscopes are processed in accordance with protocol based on national standards. These standards address how scopes are cleaned, reprocessed, and stored. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-F-2** | Between cases, the operating room(s) is cleaned with at least intermediate-level, medical-grade disinfectants. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-F-3** | There is a written policy for cleaning of spills, especially spills which may contain blood borne pathogens. |  | A  B  C-M  C | ☐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  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-F-5** | A written protocol has been developed for use by housekeeping personnel for cleaning floors, tables, walls, ceilings, counters, furniture, and fixtures of the operating suite. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **7-F-6** | Instrument handling and reprocessing areas are cleaned and maintained. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 8: CLINICAL RECORDS**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-A-6** | Electronic health records (EHR) must comply with security and privacy obligations under current HIPAA regulations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-A-7](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. | 416.47(b) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-A-10** | Clinical records are filed for easy accessibility and must be maintained in the accredited facility regardless of the location of the operating physician's office. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Pre-Operative Documentation** | | | | | |
| **[8-B-1](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | Clinical records must contain appropriate patient identification. | 416.47(b)(1) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-2](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | A pre-operative surgical safety checklist should be used for each patient and noted in the patient record. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 30-day time frame for medical history and physical examination to be completed prior to surgery.  - Address, at minimum, 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)(iii) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-6](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes medical clearance, if applicable. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-7](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | 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 | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-8](#MedWorksheet" \o "Go Back to Med Record Review Worksheet)** | 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 ASC policy.  This assessment includes, at a minimum, the patient's medical history and physical examination (if any) and documentation of any allergies to drugs and biologicals. This assessment must be placed in the patient's medical record prior to the surgical procedure. | 416.52(a)(2) Standard  416.52(a)(3) Standard  416.52(a)(4) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-10](#MedWorksheet2" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes blood pressure, pulse, respiration and temperature as taken prior to the operation. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-11](#MedWorksheet2)** | The pre-operative clinical record includes documentation of all pre-operative medications given to a patient. This record includes the date, time, amount, and route of administration. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-12](#MedWorksheet2" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes documentation of all intravenous and subcutaneous fluids given pre-operatively. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-13](#MedWorksheet2" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding any allergies and abnormal drug reactions. | 416.47(b)(5) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-14](#MedWorksheet2" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding current medications. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-15](#MedWorksheet2" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding previous serious illness. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-16](#MedWorksheet3" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding current and chronic illness. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-17](#MedWorksheet3" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding previous operations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-18](#MedWorksheet3" \o "Go Back to Med Record Review Worksheet)** | The pre-operative medical record includes responses regarding perioperative bleeding risk including medical conditions and medication taken up to the day of the operation. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-19](#MedWorksheet3" \o "Go Back to Med Record Review Worksheet)** | A pregnancy testing policy must be in place that requires a discussion and documentation of the issue with each patient, as appropriate. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-20](#MedWorksheet3" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes evidence that treating physicians or consultants are contacted in cases where warranted by the history and physical examination. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-21](#MedWorksheet3)** | The pre-operative clinical record includes documentation of appropriate laboratory procedures performed where indicated. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-22](#MedWorksheet4" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes pre-operative diagnostic studies (entered before surgery), if performed. | 416.47(b)(3) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-23](#MedWorksheet4" \o "Go Back to Med Record Review Worksheet)** | The pre-operative clinical record includes a written screening protocol for venous thromboembolism (VTE) risk. This protocol and assessment tool is to be placed in the facility manual for reference. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-24](#MedWorksheet4)** | The surgeon/proceduralist and the licensed or qualified anesthesia provider 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. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-25](#MedWorksheet4" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-B-26](#MedWorksheet4" \o "Go Back to Med Record Review Worksheet)** | Immediately before surgery a physician or anesthetist as defined at 42 CFR 410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia. | 416.42(a)(1) Standard  416.42(a)(1)(ii)  Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Informed Consent** | | | | | |
| **[8-C-1](#MedWorksheet4" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-C-2](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | Expectations, alternatives, risks, and complications are discussed with the patient, and these are documented. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-C-3](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | The informed consent provides consent for administration of anesthesia or sedatives under the direction of the surgeon, anesthesiologist, or CRNA. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-D-3](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | The ASC must document in a prominent part of the patient’s current medical record, whether or not the individual has executed an advance directive. | 416.50(c) Standard  416.50(c)(3) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: Laboratory, Pathology, X-Ray, Consultation, Treating Physician Reports, Etc.** | | | | | |
| **[8-E-1](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | Printed or written copies of these reports are kept in the medical record. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-E-2](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | All laboratory results must be reviewed and initialed by the CRNA, anesthesiologist, registered nurse, or surgeon/proceduralist. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-E-3](#MedWorksheet5" \o "Go Back to Med Record Review Worksheet)** | All abnormal laboratory results must be reviewed and initialed by the surgeon/proceduralist within one (1) week of receipt of results. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-E-4](#MedWorksheet6" \o "Go Back to Med Record Review Worksheet)** | All other reports, such as pathology reports and medical clearance reports, must be reviewed and initialed by the surgeon/proceduralist. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-E-7](#MedWorksheet6" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-E-8** | All surgical specimens must get submitted for pathological processing except those exempted by the governing body. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-E-9](#MedWorksheet6" \o "Go Back to Med Record Review Worksheet)** | The name of the pathologist must be on all pathology reports. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION F: Anesthesia Care Plan** | | | | | |
| **[8-F-1](#MedWorksheet6" \o "Go Back to Med Record Review Worksheet)** | A physician must verify that an anesthesia care plan has been developed and documented. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-2](#MedWorksheet6" \o "Go Back to Med Record Review Worksheet)** | A physician must verify that the patient or a responsible adult has been informed about the anesthesia care plan. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-4](#MedWorksheet6)** | The anesthesia care plan is based on a review of the medical record. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-5](#MedWorksheet7)** | The anesthesia care plan is based on medical history. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-6](#MedWorksheet7)** | The anesthesia care plan is based on prior anesthetic experiences. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-7](#MedWorksheet7)** | The anesthesia care plan is based on drug therapies. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-8](#MedWorksheet7)** | The anesthesia care plan is based on medical examination and assessment of any conditions that might affect the pre-operative risk. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-9](#MedWorksheet7)** | The anesthesia care plan is based on a review of the medical tests and consultations. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-10](#MedWorksheet7)** | The anesthesia care plan is based on a determination of pre-operative medications needed for anesthesia. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-F-11](#MedWorksheet8)** | The anesthesia care plan is based on providing pre-operative instructions. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION G: Intra-Operative Documentation** | | | | | |
| **[8-G-1](#MedWorksheet8" \o "Go Back to Med Record Review Worksheet)** | A “Time Out” protocol is in place, practiced, and documented in the clinical record prior to every operation.  This protocol should include a pre-operative verification process including medical records, imaging studies, and any implants identified, and be reviewed by the operating room team.  Missing information or discrepancies must be addressed in the chart 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION H: Intra-Operative Anesthetic Monitoring and Documentation** | | | | | |
| **8-H-1** | The anesthesia standards identified in Section 8-H apply to all patients who receive anesthesia or sedation/analgesia. In extreme emergencies or life-threatening circumstances, these standards may be modified; all such circumstances should be documented in the patient’s record. |  | B,  C-M,  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-2](#MedWorksheet8" \o "Go Back to Med Record Review Worksheet)** | Clinical record must contain evidence of circulation monitored by continuous EKG during procedures. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-3](#MedWorksheet8" \o "Go Back to Med Record Review Worksheet)** | Clinical record must contain evidence of circulation monitored by blood pressure documented at least every five (5) minutes. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-4](#MedWorksheet8" \o "Go Back to Med Record Review Worksheet)** | Clinical record must contain evidence of circulation monitored by heart rate documented at least every five (5) minutes. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-5](#MedWorksheet8" \o "Go Back to Med Record Review Worksheet)** | Clinical record must contain evidence of circulation monitored by pulse oximetry. Exempt if only topical and/or local anesthetic is used. | 416.47(b)(6) Standard | A,  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-6](#MedWorksheet9" \o "Go Back to Med Record Review Worksheet)** | Clinical record may contain evidence of circulation monitored by heart auscultation. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-7](#MedWorksheet9" \o "Go Back to Med Record Review Worksheet)** | Clinical record may contain evidence of circulation monitored by arterial blood pressure every 5 minutes (minimum). Circulation may be monitored by intra-arterial pressure. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-8](#MedWorksheet9" \o "Go Back to Med Record Review Worksheet)** | Clinical record may contain evidence of circulation monitored by ultrasound peripheral pulse monitor, pulse plethysmography, or oximetry. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-9](#MedWorksheet9" \o "Go Back to Med Record Review Worksheet)** | Clinical record must contain evidence of temperature monitoring when clinically significant changes in body temperature are expected. | 416.47(b)(6) Standard | C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-10](#MedWorksheet9)** | Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag, and auscultation of breath sounds are useful. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-11](#MedWorksheet9)** | Patient monitoring during anesthesia consists of end tidal carbon dioxide (ETCO2) sampling used on all sedation or general anesthetics.  Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure, or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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.  Continual end-tidal carbon dioxide 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 utilized, the end tidal carbon dioxide alarm shall be audible to the Anesthesiologist or the anesthesia care team personnel. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-H-13** | Patient monitoring during anesthesia will consist of oxygenation assessment by O2 analyzer. If an anesthesia machine is used during general anesthesia, the anesthesia machine has an alarm for low O2 concentration. |  | C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-15](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-H-16](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | An anesthesia record is maintained in which all intravenous and subcutaneous fluids given intra-operatively are recorded. | 416.47(b)(6) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-2** | Patients transferred to the PACU will be continually evaluated and monitored as needed during transport. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-3** | Patients transferred to the PACU are accompanied by a member of the anesthesia team who is knowledgeable about the patient. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-4** | Patient transfer to the PACU will include transmission of a verbal report on the patient to the PACU team from a member of the anesthesia team who accompanies the patient. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-5** | Patient transfer to the PACU will include transfer of information concerning the preoperative condition of the patient, the invasive procedure, related medication, and the anesthesia course. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-6** | Patient transfer to the PACU will include a member of the anesthesia team remains in the post-anesthesia area until the post-anesthesia care nurse accepts responsibility for the patient. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-I-7** | Family members may enter the recovery room upon approval from the physician. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION J: Post-Anesthesia Care Unit (PACU) Documentation** | | | | | |
| **[8-J-1](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes patient's time of arrival. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-2](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes the patient's post-surgical condition must be assessed and documented in the medical 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 ASC policy. | 416.52(b)(1) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-3](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes assessment of the patient by the anesthesia recovery staff, as well as by a responsible physician. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-4](#MedWorksheet10" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes a record is maintained in which all medications given to a patient are recorded, including date, time, amount, and route of administration. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-5](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes a record in which all intravenous and subcutaneous fluids given post- operatively are recorded. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-6](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | PACU documentation includes a record in which post-operative vital signs, level of consciousness, and nurses' notes are recorded until the patient is discharged from the facility. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-J-7** | Evaluation in the PACU will include observation and monitoring by methods appropriate to the patient’s condition (oxygen saturation, ventilation, circulation, and temperature). |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-J-8** | Evaluation in the PACU will include continuous pulse oximetry. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-9](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | Post-operative progress notes are recorded. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-J-10](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | There is a procedure report which includes procedure technique and findings. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION K: Discharge** | | | | | |
| **[8-K-1](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-2](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | All medical records must include a discharge diagnosis. | 416.47(b)(8)Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-3](#MedWorksheet11" \o "Go Back to Med Record Review Worksheet)** | Post-surgical needs must be addressed and included in the discharge notes. | 416.52(b)(2) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-4](#MedWorksheet12" \o "Go Back to Med Record Review Worksheet)** | Approved and standardized discharge criteria are used and recorded (e.g. Aldrete score). |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-5](#MedWorksheet12" \o "Go Back to Med Record Review Worksheet)** | 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. | 416.42(a)(2) Standard | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-8](#MedWorksheet12" \o "Go Back to Med Record Review Worksheet)** | 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 is maintained in the patient’s chart. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-9](#MedWorksheet12" \o "Go Back to Med Record Review Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[8-K-10](#MedWorksheet12)** | Patients receiving anesthetic agents other than topical or local anesthesia should 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-K-12** | Personnel assist with discharge from the recovery area. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-K-13** | Unless they are having local anesthesia only, patients are transported from the facility by wheelchair or gurney to a waiting vehicle or to another facility with a responsible adult. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION L: Operative Log** | | | | | |
| **8-L-1** | A separate 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. A loose-leaf notebook or a spiral-bound notebook does not fulfill this regulation. This log must be kept in the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-2** | An operative log must include sequential numerical listing of patients either consecutive numbering from the first case carried out in the facility or consecutive numbers starting each year. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-3** | An operative log must include date of procedure. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-4** | An operative log must include patient’s name and/or identification number. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-5** | An operative log must include record of surgery(ies) and other invasive procedures to be conducted during the case. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-6** | An operative log must include the surgeon/proceduralist’s name. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-7** | An operative log must include record of the type of anesthesia used. | 416.47(b)(6) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-8** | An operative log must include name of person(s) administering anesthesia. | 416.47(b)(6) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **8-L-9** | An operative log must include 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 9: GOVERNING BODY**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: Governing Body** | | | | | | |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-4** | The appointment of administrative personnel is documented. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-5** | The governing body 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-6** | The rules and regulations of the governing body are reviewed and revised at least annually. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-7** | The governing body: Is regulated by a governing document that has the consent of each member of the body. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-8** | The governing body: Has a policy for addressing potential conflicts of interest. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-9** | The governing body: Assumes full responsibility for reviewing and taking appropriate action on legal affairs of the ASC and its staff. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-10** | The governing body: Sets policy on how individual staff deal with each other and external parties. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-11** | The governing body: Sets policy on staff’s role in properly dealing with patients. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-12** | The governing body 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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-14** | The governing body 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-15** | The governing body is responsible for the operation and performance of the ASC including: Ensuring financial responsibility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-16** | The governing body 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-A-17** | The governing body must assure that all outside services are provided in a safe and effective manner. | 416.41(a) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 at least annually. | 416.41(b)(3) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-B-3** | The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. | 416.41(b)(1) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Extended Stays** | | | | | | |
| **9-C-1** | If overnight stays are permitted, the facility is in compliance with all applicable local and state laws and regulations. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **9-C-2** | If 23-hour stays are permitted, the facility is in compliance with all pertinent local and state laws and regulations. |  | B  C-M  C | ☐Compliant  ☐Deficient |  |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 10: QUALITY ASSESSMENT / QUALITY IMPROVEMENT / RISK MANAGEMENT**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: Quality Assessment / Quality Improvement Program / Risk Management** | | | | | |
| **10-A-1** | A licensed and qualified anesthesia provider supervising or providing care in the facility should participate in quality assurance and risk management in the facility. |  | A  B  C-M  C | ☐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. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-B-2** | The facility has a written quality improvement program implemented which includes surveys or projects that monitor and evaluate patient care. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-B-3** | The facility has a written quality improvement program implemented which includes surveys or projects that evaluate methods to improve patient care. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-B-4** | The facility has a written quality improvement program implemented which includes surveys or projects that identify and correct deficiencies within the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-B-5** | The facility has a written quality improvement program implemented which includes surveys or projects that alert the facility’s QI program to identify, track, trend, evaluate, and resolve problems. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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. |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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  B  C-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-D-2** | If peer review sources external to the facility are used to evaluate delivery of medical care, the HIPAA Business Associates Agreement is so written as to waive confidentiality of the clinical records. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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 all adverse events selected for submission to the Patient Safety Data Reporting since the preceding peer review meeting. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-D-5** | Peer review must include at a minimum:  Record of the adequacy and legibility of history and physical exam |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-D-7** | Peer review must include at a minimum:  Record of the adequacy of appropriate laboratory, EKG, and radiographic reports. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-D-8** | Peer review must include at a minimum:  Record of the adequacy of a written operative report |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **10-D-10** | Peer review must include at a minimum:  Record of the adequacy of instructions for post-operative care |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 11: PERSONNEL**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11-A-2** | All personnel are provided with a code of ethics or behavior which governs their conduct when communicating with fellow staff or the public. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Medical Director & Facility Director** | | | | | |
| **[11-B-1](#PerWorksheet2)** | 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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-B-3](#PerWorksheet2)** | The Medical Director and Facility Director must be a provider currently licensed by the state in which the facility is located. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-B-4](#PerWorksheet2)** | 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) |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-2](#PerWorksheet2)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-3](#PerWorksheet2)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-4](#PerWorksheet2)** | Each physician using the facility is credentialed and qualified for the procedures they perform. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-5](#PerWorksheet4)** | Each physician must currently be licensed by the state in which they practice. A copy of each physician’s current license must be maintained on file in the facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-7](#PerWorksheet2)** | All individuals 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 current 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  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-8](#PerWorksheet3)** | 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 facility 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.  The physician’s hospital has the right to limit the type of procedures the physician may perform within the specified scope of practice. This limitation will apply to the QUAD A-accredited facility as well.  Granting of hospital privileges outside the scope of training and practice recognized by the individual practitioner certifying board will not apply to the QUAD A-accredited facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-9](#PerWorksheet3)** | Physicians who perform procedures in facilities accredited by QUAD A must hold or demonstrate that they have held valid, unrestricted hospital privileges in their specialty at an accredited and/or licensed hospital. Only procedures included within those hospital privileges may be performed within the QUAD A accredited facility. If the privilege-granting hospital does not possess equipment or technology to allow a physician to be credentialed for a specific procedure, the physician may provide alternative evidence of training and competence in that procedure. 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 has never held privileges, or no longer holds privileges, QUAD A will accept alternate credentialing via primary source verification. Primary source verification must be re-credentialed every two (2) years. Additionally, these physicians who have primary source verification are no longer required to have hospital admitting privileges. However, the facility must have a written transfer agreement with a local hospital. It is the facility’s responsibility to conduct the primary source verification and not the physician's.  Required elements of 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 Querying and  Reporting Services (IQRS)" | | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-10](#PerWorksheet3)** | If the physician does not hold admitting privileges at the nearest acute care hospital, there must be a signed and dated document from a person in the same specialty who has admitting privileges in the nearest acute care hospital that indicates their willingness to admit the patient to the hospital. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-11](#PerWorksheet3)** | 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  - All physicians practicing in a QUAD A-accredited facility must hold, or must demonstrate that they have held, unrestricted hospital privileges in their specialty at an accredited and/or licensed acute care hospital within thirty (30) minutes of the accredited facility for all procedures that they perform within the facility. Only procedures included in those hospital privileges may be performed within the QUAD A-accredited facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-C-12](#PerWorksheet3)** | Practitioners of Pain Management would be required to 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  - All physicians practicing in an QUAD A accredited facility must hold, or must demonstrate that they have held, unrestricted hospital privileges in their specialty at an accredited and/or licensed acute care hospital within thirty (30) minutes of the accredited facility for all procedures that they perform within the facility. Only procedures included in those hospital privileges may be performed within the QUAD A accredited facility. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION D: Anesthesia Providers** | | | | | |
| **[11-D-1](#PerWorksheet2)** | If anesthesiologists, CRNAs, and/or anesthesia assistants (as certified by the NCCAA) under direct supervision of the anesthesiologist participate in patient care at the facility, they are qualified for the procedures they perform and their credentials have been verified. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-D-2](#PerWorksheet4)** | All anesthesia providers must be licensed or accredited by the state in which they practice. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11.D.3** | All anesthesiologists and CRNAs 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-D-4](#PerWorksheet4)** | The physician responsible for supervising the administration of anesthesia must have knowledge of anesthetics and resuscitative techniques. Podiatrists and oral and maxillofacial surgeons must use an anesthesiologist or a supervising physician to administer anesthesia. | 416.42(b)(1) Standard | A  B  C-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11-D-8** | The anesthesia provider(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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 regularly employed and 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 (ie, operating room, operating suite, and all patient care areas), in accordance with state/local law. |  | B  C-M  C | ☐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 professional governing bodies, where applicable. |  | B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11-F-2** | There must be a registered nurse available for emergency treatment whenever there is a patient in the ambulatory surgery facility. | 416.46(a) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11-F-4** | No nurse provides coverage in the ASC and in an adjacent clinic (or hospital) at the same time. |  | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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) 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION H: Personnel Records** | | | | | |
| **11-H-1** | 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 listed below. Please have only this data available for each employee, separate from the employee files. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **11-H-2** | There is a manual outlining personnel policies. |  | A  B  C-M  C | ☐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 OSHA, HIPAA, and ADA (Americans with Disabilities Act) guidelines.  IMPORTANT: Employee information must remain strictly confidential. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-4](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-5](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains resume of training and experience. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-6](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains current certification or license if required by the state. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-7](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains date of employment. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-8](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains description of duties. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-9](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains on-going record of continuing education. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-H-10](#PerWorksheet4" \o "Go Back to Personnel Worksheet)** | Each personnel record contains on-going record of inoculations or refusals. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION I: Personnel Training** | | | | | |
| **[11-I-1](#PerWorksheet5" \o "Go Back to Personnel Worksheet)** | Each personnel record has evidence of annual hazard safety training. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-2](#PerWorksheet5" \o "Go Back to Personnel Worksheet)** | Each personnel record has evidence of annual blood borne pathogen training. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-3](#PerWorksheet5" \o "Go Back to Personnel Worksheet)** | Each personnel record has evidence of annual universal precaution training. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-4](#PerWorksheet5" \o "Go Back to Personnel Worksheet)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-5](#PerWorksheet" \o "Go Back to Personnel Worksheet)** | 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 patient population. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-6](#PerWorksheet5" \o "Go Back to Personnel Worksheet)** | The operating room personnel have knowledge to treat cardiopulmonary and anaphylactic emergencies. At least one member of the operating room team, preferably the physician, pediatric dentist, or the anesthesia provider, holds current PALS certification and/or ACLS certification, if appropriate. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-10](#PerWorksheet5)** | The operating room personnel are familiar with equipment and procedures utilized in the treatment of emergencies discussed in standards section 5-C. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-11](#Stand11i11)** | If a gas sterilizer or Automated Endoscope Reprocessor (AER) is used, personnel are thoroughly familiar with the operating instructions. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[11-I-12](#PerWorksheet6)** | Facility maintains documented training of appropriate personnel related to scope cleaning, reprocessing, and storing, as applicable to individual duties. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION J: Vaccination Status** | | | | | |
| ***11-J-1*** | *The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.* | *416.51(c)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-2*** | *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:*  *-Facility employees;* | |  | | --- | | *416.51(c)(1)(i)* |   *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-3*** | *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:*  *-Licensed practitioners;* | *416.51(c)(1)(ii)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-4*** | *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:*  *-Students, trainees, and volunteers; and* | *416.51(c)(1)(iii)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-5*** | *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:*  *-Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.* | *416.51(c)(1)(iv)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-6*** | *The policies and procedures of this section do not apply to the following facility staff:*  *Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in standards 11-J-2, 11-J-3, 11-J-4, and 11-J-5; and* | *416.51(c)(2)(i)*  *Standard* | A  B  C-M  C | Compliance Note –  Not Applicable | Enter observations of non-compliance, comments or notes here. |
| ***11-J-7*** | *The policies and procedures of this section do not apply to the following facility staff:*  *Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in standards 11-J-2, 11-J-3, 11-J-4, and 11-J-5.* | *416.51(c)(2)(ii)*  *Standard* | A  B  C-M  C | Compliance Note –  Not Applicable | Enter observations of non-compliance, comments or notes here. |
| ***11-J-8*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring all staff specified in standards 11-J-2, 11-J-3, 11-J-4, and 11-J-5 (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine, prior to staff providing any care, treatment, or other services for the facility and/or its patients;* | *416.51(c)(3)(i)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-9*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring that all staff specified in standards 11-J-2, 11-J-3, 11-J-4, and 11-J-5 are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;* | *416.51(c)(3)(ii)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-10*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;* | *416.51(c)(3)(iii)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-11*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in standards 11-J-2, 11-J-3, 11-J-4, and 11-J-5;* | *416.51(c)(3)(iv)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-12*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;* | *416.51(c)(3)(v)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-13*** | *The policies and procedures must include, at a minimum, the following components:*  *A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;* | *416.51(c)(3)(vi)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-14*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;* | *416.51(c)(3)(vii)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-15*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:*  *All information specifying which of the authorized or licensed COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and* | *416.51(c)(3)(viii)*  *416.51(c)(3)(viii)(A)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-16*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:*  *A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;* | *416.51(c)(3)(viii)(B)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-17*** | *The policies and procedures must include, at a minimum, the following components:*  *A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and* | *416.51(c)(3)(ix)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| ***11-J-18*** | *The policies and procedures must include, at a minimum, the following components:*  *Contingency plans for staff who are not fully vaccinated for COVID–19.* | *416.51(c)(3)(x)*  *Standard* | A  B  C-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 12: State Supplements**

| **ID** | **Standard** | **CMS Ref** | **Class** | **Score** | **Findings/Comments** |
| --- | --- | --- | --- | --- | --- |
| **SUB-SECTION A: ASC - Florida** | | | | | |
|  | *If the facility is not located in Florida, please select N/A for section 12-A.* |  |  | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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 | ☐Compliant  ☐Deficient | 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 | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[12-A-9](#PerWorksheet6)** | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **12-A-10** | The governing body of the organization is responsible for overseeing the program of risk management. |  | A  B  C-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | 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  B  C-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | 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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 13: Life Safety Code**

| **ID** | **Standard** | **CMS Ref** | **Class** | **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐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-M  C | ☐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-M  C | ☐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. | 416.44(b)(2) Standard | A  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **[13-A-8](#ICWorksheet13A8" \o "Return to Infection Control Worksheet)** | 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  B  C-M  C | ☐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-M  C | ☐Compliant  ☐Deficient | Enter observations of non-compliance, comments or notes here. |
| **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(c) Standard | A  B  C-M  C | ☐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-M  C | ☐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-M  C | ☐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** 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]***

**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.”

**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\_locations.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.

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

(i) NFPA 99, Standards for Health Care Facilities Code of the National FireProtection Association 99, 2012 edition, issued August 11, 2011.

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

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

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

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

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

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

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

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

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

***[42 CFR 416.44(f)(1)(i-xi)]***



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