Objectives

- To provide an overview of chapter reorganization
- To provide a summary of standards revisions
- To provide education on the new standards
- To highlight frequently cited standards and provide clarification
Overview of Revisions

- Revision of chapter order
- Reorganization of standards to new chapter order
  - Middle standard number (00.00.00) designation of different focus within the chapter
- Reorganization within chapters
  - Begin with oversight/responsibility
  - Flow chronologically
  - Address provision of care/service
- Reduce redundancies
- Focus on requirements
Key to Updates

- Purple text notates any additions to the 2021 standards
- Strikethrough notates any deleted text from the 2021 standards
# Chapter Listings

- **Reorganization of chapters for areas of focus:**
  - Organization-wide
  - Services and Patient Care
  - Facility-oriented

- **Separated:**
  - Surgical and Anesthesia Services
  - Laboratory and Radiological Services

<table>
<thead>
<tr>
<th>Current Chapter #</th>
<th>New Chapter #</th>
<th>Chapter Name</th>
<th>New Chapter Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Governing Body and Management</td>
<td>Governing Body and Management</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Administration</td>
<td>Administration and Human Resources</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Surgical Services</td>
<td>Medical Staff</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>Quality Assessment</td>
<td>Quality Assessment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Performance Improvement</td>
<td>Performance Improvement</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>Environment</td>
<td>Infection Prevention and Control</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>Medical Staff</td>
<td>Patient Rights</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>Nursing Services (Chapter Deleted)</td>
<td>Emergency Management</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>Medical Records</td>
<td>Medical Records</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>Pharmaceutical Services</td>
<td>Patient Assessment and Discharge</td>
</tr>
<tr>
<td>10</td>
<td>10</td>
<td>Laboratory and Radiology Services</td>
<td>Surgical Services</td>
</tr>
<tr>
<td>11</td>
<td>11</td>
<td>Patient Rights</td>
<td>Anesthesia Services</td>
</tr>
<tr>
<td>12</td>
<td>12</td>
<td>Infection Control</td>
<td>Pharmaceutical Services</td>
</tr>
<tr>
<td>13</td>
<td>13</td>
<td>Patient Admission, Assessment and Discharge</td>
<td>Laboratory Services</td>
</tr>
<tr>
<td>14</td>
<td>14</td>
<td>Life Safety</td>
<td>Radiology Services</td>
</tr>
<tr>
<td>15</td>
<td>15</td>
<td>Emergency Management</td>
<td>Physical Environment</td>
</tr>
<tr>
<td>16</td>
<td>16</td>
<td>Life Safety</td>
<td>Life Safety</td>
</tr>
</tbody>
</table>
Standards Related to CfCs
Summary of New CfC-Related Standards

- Details will be discussed in later slides
- Requirements in standards are not truly new but were embedded in other standards

**CMS CfC**

- 01.01.03 Approval of the Scope of Procedures
- 03.01.01 Professional Staff: Applications
- 14.00.00 Condition for Coverage: Radiological Services
### Summary of New Standards (not CfC)

Details will be discussed in applicable chapters.

<table>
<thead>
<tr>
<th>ACHC</th>
<th>ACHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>02.00.01 Administrative Leadership</td>
<td>11.01.01 Director of Anesthesia Services</td>
</tr>
<tr>
<td>02.00.02 Administrative Leadership Responsibilities</td>
<td>11.01.03 Anesthesia and Sedation Administration</td>
</tr>
<tr>
<td>02.01.02 Employee Requirements</td>
<td>11.02.01 Policies, Procedures, and Protocols for Administration of Moderate Sedation</td>
</tr>
<tr>
<td>02.01.08 Staff Training: identification of Patients at Risk for Harm</td>
<td>11.03.01 Emergency Training</td>
</tr>
<tr>
<td>03.02.01 Management of an Incapacitated or Impaired Healthcare Provider</td>
<td>12.00.08 Preparation Area</td>
</tr>
<tr>
<td>04.01.08 Use of Thresholds for Benchmarking</td>
<td>12.02.01 Disposal of Drugs and Biologicals</td>
</tr>
<tr>
<td>05.03.02 Internal Laundry</td>
<td>12.02.02 Security of Drugs and Biologicals</td>
</tr>
<tr>
<td>07.03.03 After-Action Reports</td>
<td>13.02.03 Manufacturer’s Instructions for Waived Testing</td>
</tr>
<tr>
<td>10.01.04 Removed Specimens</td>
<td>13.02.04 Quality Control for Waived Tests</td>
</tr>
<tr>
<td>10.04.01 Laser, Light-Based, and Other Energy Emitting Technologies Officer</td>
<td>13.03.03 Certificate for PPM Procedures</td>
</tr>
<tr>
<td>10.04.02 Laser, Light-Based, and Other Energy Emitting Technologies Policies</td>
<td>13.03.04 PPM Director</td>
</tr>
<tr>
<td>10.04.03 Staffing for the Use of Laser, Light-Based, and Other Energy Emitting Technologies</td>
<td>13.03.05 PPM Personnel</td>
</tr>
<tr>
<td>10.04.04 Warning Signs for Laser, Light-Based, and Other Energy Emitting Technologies</td>
<td>13.03.06 PPM Policies and Procedures</td>
</tr>
<tr>
<td>10.04.05 Personal Protective Equipment for Laser, Light-Based, and Other Energy Emitting Technologies</td>
<td>13.06.02 Work Areas</td>
</tr>
<tr>
<td>11.00.01 Anesthesia and Sedation Levels</td>
<td>14.02.05 Radioactive materials</td>
</tr>
</tbody>
</table>
Summary of Deleted Standards (not CfC)

- Some standards combined into other standards
- Redundant standards deleted
- QAPI standards are reviewed in QAPI chapter

<table>
<thead>
<tr>
<th>ACHC (not CMC CfC)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>01.02.08</td>
<td>Annual Review of the Accounting System</td>
</tr>
<tr>
<td>02.02.03</td>
<td>Phone Answering Device Provides organization Information</td>
</tr>
<tr>
<td>02.03.01</td>
<td>Compliance Program</td>
</tr>
<tr>
<td>02.03.02</td>
<td>Compliance Program Communication System</td>
</tr>
<tr>
<td>02.03.04</td>
<td>Compliance Program Periodic Audit</td>
</tr>
<tr>
<td>03.02.01</td>
<td>Operating Room Register</td>
</tr>
<tr>
<td>03.04.01</td>
<td>Laser Procedures</td>
</tr>
<tr>
<td>03.04.02</td>
<td>Laser Procedures Privileges</td>
</tr>
<tr>
<td>03.04.04</td>
<td>Laser Procedures QAPI</td>
</tr>
<tr>
<td>04.01.04</td>
<td>QAPI Committee Reviews Data</td>
</tr>
<tr>
<td>05.03.04</td>
<td>Handicapped Parking</td>
</tr>
<tr>
<td>05.03.06</td>
<td>Clean Environment</td>
</tr>
<tr>
<td>05.03.07</td>
<td>Adequate Space</td>
</tr>
<tr>
<td>05.03.09</td>
<td>Adequate Reception Areas and Restrooms</td>
</tr>
<tr>
<td>05.03.12</td>
<td>Exam/Consult Rooms</td>
</tr>
<tr>
<td>05.03.13</td>
<td>Changing Rooms</td>
</tr>
<tr>
<td>05.03.15</td>
<td>Housekeeping Services</td>
</tr>
<tr>
<td>10.02.07</td>
<td>Laboratory Integrated with QAPI</td>
</tr>
<tr>
<td>10.04.01</td>
<td>Contracted Radiological Services are Monitored</td>
</tr>
<tr>
<td>12.01.14</td>
<td>Clean Linen</td>
</tr>
</tbody>
</table>
Chapter 1
Governing Body and Management
No Significant Changes

- 01.00.00 Definitions
- 01.00.01 Condition for Coverage: Compliance with State Licensure Law
- 01.01.01 Condition for Coverage: Governing Body
- 01.01.02 (previously 01.02.01) Governing Body Maintains Documentation of Entity
Standard Elimination

The following standards were incorporated into the newly revised standards and are no longer listed as individual:

- 01.02.06 Governing Body Functions Through Committees or a Committee-of-the-Whole
- 01.02.08 Annual Review of the Accounting System
- 01.02.01 Governing Body Selects ASC Leadership
01.01.03 Governing Body Responsibilities

The governing body must establish bylaws or similar documents, such as policies, that define its responsibilities, including but not limited to:

1. Description of how members of the governing body are selected, the number of members, terms in office, duties, responsibilities, and procedures for removal.
2. Frequency of governance meetings; at least annually.
3. Requirement to maintain minutes reflecting attendance and deliberations leading to actions.
4. Committee definition and authorization, if used.
5. Adoption and periodic review of governance bylaws/governance policies.
6. Implementation of an effective fiscal accounting system(s).
7. Review and appropriate action on all legal and ethical matters as they relate to the ASC and its staff.
8. Ensuring compliance with the patients’ rights policy.
9. Establishing a non-discrimination policy regarding race, creed, gender identity, and national origin that applies to staff and patients and is in compliance with applicable non-discrimination laws.
10. Provision of resources needed to maintain safe, quality care and services at the ASC. These resources include:
   - Personnel.
   - Equipment and supplies.
   - Provision for a safe environment.
11. Disaster preparedness.
01.01.04 Approval of the Scope of Procedures

The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

§416.45(b)

The governing body approves the written scope of procedures performed and anesthesia/sedation administered in the organization at least every three years and changes to the written scope must be approved by the governing body.
01.01.05 Accounting System (Current 01.02.07)

The governing body approves a financial accounting system, including a short and long-term budgeting system and financial management that adequately addresses the resource needs of the organization based on the approved scope of services and prepared according to generally accepted accounting principles.
The governing body establishes a leadership structure to support the operations of the facility.

The governing body identifies the individual(s) responsible for day-to-day functions of the ASC and the formal means of accountability for all staff.

- The governing body develops an organizational chart that identifies:
  - The organizational lines of authority and communication.
  - The liaison with the governing body.
When appropriate, the governing body appoints an individual for medical oversight of the ASC and defines the individual’s qualifications and management responsibilities in a written position description.

If no medical director is appointed, the ASC will designate a single individual as chief of service (or other title) for medical oversight of the ASC.

The medical director is responsible for assuring medical staff compliance with all standards.

The individual must be accountable to the governing body.
01.02.01 Contract Services (Current 01.01.02)

When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

§416.41(a)
01.02.02 Hospitalization and Transfer (Current 01.01.03)

1. 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.

2. This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of 42 Code of Federal Regulation.

3. The ASC must periodically provide the local hospital its written notice of operations and patient population served.

4. The ASC must:
   - Have a written transfer agreement with a hospital.
   OR
   - Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital.

§416.41(b)(1)
§416.41(b)(2)
§416.41(b)(3)
Chapter 2
Administration and Human Resources
No Significant Changes

- 02.00.04 Nursing Services Staffing (Current 07.00.02)
- 02.01.10 Assessment of Staff Competency (Current 02.01.08)
- 02.02.01 Credentialing of the Employees of Healthcare Professionals (Current 06.01.04)
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual:
  - 02.02.03 Phone Answering Device Provides ASC Information
  - 02.03.01 Compliance Program
  - 02.03.02 Compliance Program Communication System
  - 02.03.04 Compliance Program Period Audit
02.00.01 Administrative Leadership (NEW)

The administrator must report to the governing body and is responsible for the day-to-day operations of the organization.
02.00.02 Administrative Leadership Responsibilities (NEW)

The administrative leader is responsible for carrying out all duties assigned or delegated to him/her by the governing body, which may include but are not limited to:

- Oversight of Quality Assessment/Performance Improvement.
- Monitoring and reviewing for ethical behavior.
- Annual review and monitoring of patient rights.
- Evaluation of equipment.
- Establishment of a staff development program.
- Establishment of an emergency response protocol.
02.00.03 Condition for Coverage: Nursing Services (Current 07.00.01)

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

§416.46 Note: This is a CMS condition level requirement.
The ASC leadership ensures there is an assessment of potential risk areas related to fraud and abuse. **The assessment includes a periodic audit (at least yearly and more frequently if errors are found) to verify that:**

- Bills are correctly coded and accurately reflect the services provided.
- Services or items provided are reasonable and necessary.
- Healthcare records contain sufficient documentation to support charges.

**Coding and billing:**

**Reasonable and necessary services:**

**Documentation:**

**Improper inducements, kickbacks and self-referrals:**
02.00.06 Administrative Processes: Required Policies (Current 02.02.01)

The ASC leadership has established policies addressing:

1. Key administrative functions.
2. Scheduling of appointments procedures.
3. Cancellation of appointments procedures.
4. Rescheduling of appointments procedures.
5. Patient portal messaging.
6. Documentation of telephone or electronic messages including the date and time of the call, message, and timely forwarding to the appropriate individual. Process for handling telephone messages including documentation of the date and time of the call, message, and timely forwarding to the appropriate individual.
02.00.07 Hours of Operation (Current 02.02.02)

The ASC has mechanisms to provide sufficient information for a patient with “after-hours” questions, including **must have a process to inform patients of:**

- **Who to call/where to go or what to do in the event of an after-hours for an emergency.**
- **What to do for routine care inquiries.**
02.01.01 Human Resources Policies

The ASC leadership has written Human Resource (HR) policies and procedures that:

▪ Ensure personnel and contract individuals are licensed or meet requirements consistent with State or local laws.

▪ Establish that all providers whose license, certification or registration lapses or is placed under revocation, suspension, stipulation, etc., conform to all provisions.

▪ Are reviewed and approved on an annual basis by the CEO-Administrator or designated individual if only minor changes have been made.

▪ Are available to each employee.
02.01.02 Employee Requirements (NEW)

The organization must verify that all employees, including contracted employees, meet applicable requirements for employment, including but not limited to:

- Licensure.
- Certification.
- Registration.
- Permits (such as food handler’s permits).
- Qualifications as defined in the job description.
02.01.03 Position Descriptions

The ASC must have written job descriptions for all personnel positions including leadership, contract staff, and medical employees not covered by the credentialing and privileging of healthcare professionals.

Position descriptions include:

2. Duties and responsibilities in accordance with the State Scope of Practice Acts.
3. Licensure, certification, or registration in accordance with applicable governmental laws and regulations and consistent with state scope of practice. Qualifications for the position including education, training, experience, skills, license and/or certification.
02.01.04 Adequate Staffing Requirements (Current 02.01.02)

The ASC leadership has a policy that approved by the medical staff that establishes staffing and training to support all its functions of the facility, including:

- Adequate staffing to support all administrative functions **and approved surgical procedures**.
- A mechanism for routinely assessing the adequacy of staff to meet the level of services offered.
- Minimum staffing of personnel and training requirements (for personnel) for each procedure room, suite, recovery unit and other critical areas as determined by the ASC.
02.01.05 Personnel Records (Current 02.01.04)

The ASC must maintain personnel records for **each member of the ASC staff, including employees** and contracted staff.
02.01.06 Orientation Plan (Current 02.01.05)

The ASC must have a written orientation plan that orients the new employee to the organization and the specific duties they will perform.

Organizational training must include:

1. Ethics and Corporate Compliance, if applicable.
2. Patients’ rights.
3. Fire safety.
4. Quality improvement, including adverse events.
5. Assessment of patient’s risk for self-harm.
6. Patient confidentiality.
7. Infection control, including blood-borne pathogens.
8. Management of an incapacitated or impaired healthcare provider.
9. Handling hazardous waste.
10. Communication with outside entities.
02.01.07 Staff Training (Current 02.01.06)

The organization has a written plan for providing training when necessary and at least annually.

The ASC must develop a plan to provide continuous on-the-job training:
- The written training plan is supported with lesson plans.
- The ASC conducts annual staff training.
- Annual training reviews the seven requirements of orientation. (See standard 02.01.05.)
02.01.08 Staff Training: Identification of Patients at Risk for Harm (NEW)

Organization staff must be trained to identify patients at risk for harm to self or others at the time of new employee orientation and annually thereafter.
Chapter 3

Medical Staff
No Significant Changes

- 03.00.04 Other Practitioners Granted Clinical Privileges (Current 06.00.05)
- 03.01.03 Use of a Credentials Verification Organization (CVO) (Current 06.01.05)
- 03.01.04 Granting Privileges (Current 06.00.02)
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual:
  - 06.01.04 moved to 02.02.01
03.00.01 Condition for Coverage: Medical Staff (Current 06.00.01)

The Medical Staff of the ASC must be accountable to the Governing Body.

§416.45
03.00.02 Organized Medical Staff (Current 06.01.01)

The Governing Body must provide for an organized professional medical staff structure.

If the medical staff is organized into a specific body, there must be a written process for the governing body to approve the medical staff bylaws, rules and regulations and to hear appeals and conduct hearings from the professional staff members.
03.00.03 Medical Staff Policies (Current 06.01.02)

The medical staff must establish written policies in accordance with applicable governmental laws and regulations. These written policies may be included in the medical staff bylaws and rules and regulations, if applicable. The policies must address:

- Categories of practitioners eligible for privileges.
- A definition of “physician” that is consistent with state and federal regulations.
- Process for initial and reappointment to the medical staff.
- Credentialing process.
- Privileging process.
- Periodic review of the clinical privileges offered.
- A code of ethics.
The governing body, in conjunction with the medical staff, must establish policies in accordance with State and Federal regulations including:

1. The categories of practitioners eligible for privileges:
   a. Physicians
   b. Non-physician practitioners, as applicable, including CRNAs, Nurse Practitioners, Physician Assistants, RN First Assistants, Anesthesia Assistants, and etc.
   c. Contracted or part-time licensed professional staff

2. The delineation of privileges offered for each category of practitioner, consistent with procedures offered.

3. The periodic review of the clinical privileges offered at the ASC.

4. Procedure for the removal of a physician demonstrating signs of impairment or illness during a surgical procedure.
The credentialing and privileging process including:

- Requirements for initial application and re-application.
- Eligibility requirements for appointment including education, training, and experience.
- Eligibility requirements including licensure, registrations, and certifications, as applicable.
- Requirements for personal references.
- Evidence of current competencies including procedural logs and peer-review activities.
- Requirements that the governing body grants privileges to those practitioners meeting the established eligibility requirements based on medical staff recommendations.
- Requirements for medical malpractice insurance from acceptable carrier and required coverage amounts.
- Verification of information provided on the application.
- Establishment of an appointment cycle that is compliant with applicable laws and regulations and no longer than 36 months.
- The reappraisal process used to evaluate the performance of each practitioner.
- Notification to the applicant of the governing body's decision to grant or deny privileges.
- A statement of nondiscrimination and assurance that the criteria for application/reapplication does not include sex, race, creed, national origin, handicap or other considerations not impacting the applicant's ability to discharge the privileges for which s/he has applied.

- Requirement that applicants adhere to the ASC's Code of Ethics.
New Standard 03.01.01

- History:
  - Current standard 06.00.02 addressed both credentialing and privileging, with a focus on granting privileges.
    - Members of the Medical Staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted.
    - The ASC grants privileges in accordance with recommendations from qualified medical personnel.
      §416.45(a)
  - The expectations for credentialing were further addressed in current standard 06.01.03, an ACHC standard not linked to a CfC.
New Standard 03.01.01 continued

New:

- Standard 03.01.01 is linked to the CfC §416.45(a), now separating credentialing from privileging and incorporating relevant requirements of current 06.01.03.
  - Applications for Medical Staff Privileges
    - Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted. §416.45(a)
  - Privileging is now addressed at 03.01.04.
  - Granting Privileges
    - The ASC grants privileges in accordance with recommendations from qualified medical personnel. §416.45(a)
03.01.01 Applications for Medical Staff Privileges (Current 06.01.03)

Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted.

§416.45(a)

A credentials file is initiated for each applicant requesting medical staff privileges. The governing body has established processes to verify the information provided with the application for appointment or reappointment.
03.01.02 Credentialing Files (Current 06.00.03)

A credentialing file is maintained for each applicant requesting medical staff privileges.

Members of the Medical Staff must be legally and professionally qualified for the positions to which they are appointed and for performance of privileges granted.

The ASC grants privileges in accordance with recommendations from qualified medical personnel.

§416.45(a)
Medical staff privileges must be periodically reappraised by the ASC.

The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

§416.45(b)

The ASC has a policy, approved by the medical staff and the governing body, that addresses the process for the medical staff, as a body or as a committee, to review and make recommendations to the governing body on all applications for appointment and reappointment to the professional staff at least every 36 months.
03.02.01 Management of an Incapacitate or Impaired Healthcare Provider (New)

The medical staff has written provisions for identifying and managing an incapacitated or impaired healthcare provider, and these are known to staff.
Chapter 4
Quality Assessment Performance Improvement (QAPI)
No Significant Changes

- 04.00.01 Quality Assessment and Performance Improvement
- 04.01.01 QAPI Plan (Current 04.01.02)
- 04.01.05 Program Activities: Set Priorities *(Removed detailed definitions and descriptions)*
- 04.01.06 Quality Indicators: Collection of Data (Current 04.00.04) *(Removed detailed definitions and descriptions)*
- 04.01.10 Documentation of Projects (Current 04.00.10)
- 04.02.02 Performance Improvement Activities: Review of Transfusions and Transfusion Reactions (Current 04.01.08)
- 04.02.05 Performance Improvement Activities: Review of Clinical Records (Current 04.01.07)
- 04.02.07 Performance Improvement Activities: Patient Complaints and Grievances (Current 04.01.11)
- 04.03.02 Risk Management: Implementation of Preventative Strategies (Current 04.00.08) *(Removed detailed definitions and descriptions)*
- 04.03.02 Risk Management: Implementation of Preventative Strategies (Current 04.00.08)
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual
  - 04.01.04 QAPI Committee Reviews Data
04.00.02 Governing Body Responsibilities (Current 04.00.11)

The governing body must ensure that the QAPI program:

1. Is defined, implemented, and maintained by the ASC.
2. Addresses the ASC’s priorities and that all improvements are evaluated for effectiveness.
3. Specifies data collection methods frequency and details.
4. Clearly establishes its expectations for safety.
5. Adequately allocates sufficient staff, time, information systems, and training to implement the QAPI program.

§416.43(e)(1)  
§416.43(e)(2)  
§416.43(e)(3)  
§416.43(e)(4)  
§416.43(e)(5)
04.01.01 QAPI Plan (Current 04.01.02)

The ASC must have an annual written quality plan that details all planned how quality activities for the year will be performed. Annually, the annual quality plan is approved by the ASC leadership.

§416.43(a)
04.01.02 QAPI Program Scope of Indicators (Current 04.00.02)

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)
04.01.03 Quality Indicators: Contracted Services (Current 04.01.02)

The ASC’s must have an annual quality plan which details all planned activities for the year includes assessment of contractor services.

- The annual quality plan is approved by the leadership.
- Contractor services must be included in the QAPI program.

§416.41(a)
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)
04.01.07 Use of Data Collected

The ASC must use the data collected to:

- Monitor the effectiveness and safety of its services, and quality of its care.
- Identify opportunities that could lead to improvements and changes in its patient care.

§416.43(b)(2)(i)
§416.43(b)(2)(ii)
04.01.08 Use of Thresholds for Benchmarking (NEW)

The program must establish goals based on performance metrics in order to evaluate services furnished in the organization.
04.01.09 Performance Improvement Projects (Current 04.00.09)

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)
04.01.11 QAPI Implementation
Oversight

QAPI activities are directed by an individual designated by the governing body or QAPI committee.

If an individual is chosen, this individual has evidence of training in the principles of QAPI and may involve others in the organization and/or outside consultants with training and experience in quality management to assist in developing and implementing meaningful studies with the goal of continuous improvement.

The ASC leadership has defined—

A multidisciplinary QAPI Committee / function.
The individual(s) in charge of the Quality Assurance Performance Improvement (QAPI) program. This individual has evidence of training in the principles of quality assurance.
The Quality Committee/ function must meet at least quarterly.

Written minutes are maintained for each QAPI meeting.
The ASC must write an annual end-of-year report based upon the annual plan, as an integral part of the QAPI program, which details all quality activities and their progress or resolution during the year.

The report must be submitted to the governing body for review and approval.
04.02.01 Performance Improvement Activities: Unanticipated Patient Events (Current 04.00.07)

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)
Performance improvement activities must review-track all unplanned transfers to a higher level of care to determine if appropriate care and evaluation had been rendered.
04.02.04 Performance Improvement Activities: Review of All Deaths in ASC (Current 04.01.05)

Performance improvement activities must **review-track** any deaths occurring in the ASC or **after transferring to a higher level of care** and determine if appropriate care and evaluation had been rendered.
04.02.06 Performance Improvement Activities: Patient Satisfaction Surveys (Current 04.01.09)

- The ASC must formally survey patients and families to determine the level of satisfaction with at least:
  - The quality of care delivered.
  - The environment of care.
  - The caregiving process.
A Risk Management Program assesses risks inherent to a specific organization.

The Risk Management Program reviews data to identify potential risks including but not limited to:

- Unanticipated events.
- Deaths.
- Complaints and grievances.
- Patient falls.
- Medication errors.
- Medical malpractice claims.
- Complaints.
- Data security risks.

The Risk Management program incorporates review of individual events and quality improvement activities. The organization has identified a process for staff to report all unanticipated events.
Chapter 5

Infection Prevention and Control
No Significant Changes

- 05.00.01 Condition for Coverage: Infection Control (Current 12.00.01) (Removed detail)
- 05.00.04 Infection Prevention and Control Program Officer (Current 12.00.04)
- 05.00.05 Integration with Quality Assurance and Performance Improvement (Current 12.00.05)
- 05.01.02 Cleaning and Decontaminating Instruments (Current 12.01.04)
- 05.01.03 Cleaning and Decontaminating Instruments: Personnel Responsibilities (Current 12.01.12)
- 05.01.04 Monitor Effectiveness of Sterilization Cycles (Current 12.01.03)
- 05.01.06 Load Control Numbers (Current 12.01.05)
- 05.02.01 Post-Exposure Protocol (Current 12.01.13)
- 05.04.01 COVID-19 Vaccination of Staff (Current 12.02.01)
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual:
  - 12.01.04 Clean Linen
05.00.02 Infection Prevention and Control Program Development (Current 12.00.03)

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)
The Infection Prevention and 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)
05.00.06 Sanitary Environment (Current 12.00.02)

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

§416.51(a)
05.01.01 Decontamination and Sterilization Policies and Procedures (Current 12.01.01)

The ASC has written policies and procedures for decontamination and sterilization that are approved by the medical staff that addresses the following practices, as appropriate, based on the manufacturer’s instructions and nationally recognized guidelines and approved by the medical staff.

1. Decontamination and cleaning of surgical instruments
2. Monitoring effectiveness of sterilization cycles
3. Sterilization data requirements
4. Load control numbers
5. Cold sterilization
6. Immediate Use Steam Sterilization (IUSS)
7. Preparing, assembling, wrapping, and distribution of sterile equipment and supplies
8. Storage of sterile packages
9. Monitoring supplies
10. Loaner instruments
05.01.05 Sterilization Data Requirements (Current 12.01.04)

A policy requires recording and maintaining temperature and pressure readings for every sterilized load.
05.01.07 Cold Sterilization or High-Level Disinfection (Current 12.01.06)

The ASC has written policies and procedures related to cold sterilization and high-level disinfection procedures used.
05.01.08 Immediate Use Steam Sterilization (Current 12.01.07)

The ASC is in compliance with its has written policies related to immediate use steam sterilization (IUSS).

IUSS practices are based on current nationally recognized infection control guidelines and standards of practice.

Surgical disinfection and sterilization procedures are expected to be consistent with accepted standards of practice to prevent the transmission of infectious disease and protect the health and safety of patients.
05.01.09 Preparing, Assembling, Wrapping, and Distributing Sterile Equipment and Supplies (Current 12.01.08)

The ASC has written policies related to preparing, assembling, wrapping, and distributing sterile equipment and supplies.
The ASC is in compliance with its has written policies related to:

• The shelf life for each type of sterile product.
• Storage of sterile packages is in compliance with the manufacturer’s instructions.
05.01.11 Process for Monitoring Supplies (Current 12.01.10)

The ASC is in compliance with its has written policies and procedures related to:

- Monitoring of sterile packages and supplies to ensure none have reached expiration date.
- Monitoring of sterile packages to ensure the integrity has not been compromised.
- Disposal/reprocessing of patient care supplies/equipment that are outdated or contaminated.
- Monitoring of product recalls and removing relevant products accordingly.
The ASC has policies and procedures approved by the medical staff that address the inspection, decontamination, and sterilization of instruments brought into the ASC on a temporary basis based on manufacturer’s recommendations.
05.03.01 Linen Management (Current 12.01.15)

The ASC has written policies and procedures approved by the medical staff that address the processing of linen to reduce the likelihood of cross-contamination and provide a safe environment.

Contaminated linen must be placed in collection bags, hampers or other holding devices, which reduce the potential for particles becoming airborne and/or liquids dripping from, or absorption into, the holding device.
05.03.02 Internal Laundry (NEW)

An organization providing its own laundry services has written policies and procedures based on nationally recognized guidelines and/or recommendations.
No Significant Changes

- 06.00.01 Condition for Coverage: Patient Rights (Current 11.00.01)
- 06.00.02 Standard Level: Posting the Notice of Patient Rights (Current 11.00.02)
- 06.00.03 Notice of Patient Rights: Provided to the Patient (Current 11.00.03)
- 06.00.05 Advance Directives (Current 11.00.06)
- 06.00.07 Disclosure of Financial Interests or Ownership (Current 11.00.05)
- 06.04.01 Confidentiality of Clinical Records (Current 11.02.04)
06.00.04 Informed Consent (New, from current 11.02.01)

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)
06.00.06 Representation of Patients Declared Incompetent by the State (Current 11.02.02)

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.

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)(2)
§416.50(e)(3)
06.01.01 Exercise of Rights and Respect for Property and Person (Current 11.02.01)

The patient has the right to **the following**: Be free from any act of discrimination or reprisal.

Voice grievances regarding treatment or care that is (or fails to be) provided.

Be fully informed about a treatment or procedure and the expected outcome before it is performed.

§416.50(e)(1)(i)
§416.50(e)(1)(ii)
§416.50(e)(1)(iii)
06.01.02 Privacy and Safety (Current 11.02.03)

The patient has the right to:

• Personal privacy.
• Receive care in a safe setting.
• Be free from all forms of abuse or harassment.

§416.50(f)(1)
§416.50(f)(2)
§416.50(f)(3)
The patient has the right to voice grievances regarding treatment or care that is (or fails to be) provided.

\$416.50(e)(1)(ii)

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. The procedure must meet these following criteria:

- The grievance process must specify time frames for review of the grievance and the provision of a response.
- 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.
- 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 result of the grievance process, and the date the grievance process was completed.

\$416.50(d)
\$416.50(d)(4)
\$416.50(d)(5)
\$416.50(d)(6)
06.02.02 Documentation of Grievances (Current 11.01.02)

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.

The following criteria must be met:

• All alleged violations/grievances relating, but not limited, to mistreatment, neglect, verbal, mental, sexual, or physical abuse must be fully documented.
• All allegations must be immediately reported to a person in authority in the ASC.
• Only substantiated allegations must be reported to the State authority or the local authority, or both.

§416.50(d)(1)
§416.50(d)(2)
§416.50(d)(3)
06.03.01 Use of Restraints (NEW)

The patient has the right to be free from unnecessary use of physical or chemical restraint as a means of coercion, convenience, or retaliation.
Chapter 8
Medical Records
No Significant Changes

- 08.00.01 Condition for Coverage: Medical Records
- 08.00.03 Form and Content of the Medical Record
- 08.01.02 Medical Record Storage
08.00.02 Organization

The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

§416.47(a)

The ASC will maintain patient records for five years or longer in accordance with applicable laws and regulations.
08.01.01 Release of Information

The ASC has a **written** policy that addresses **the release of patient records and other information.**

- The confidentiality of patient records.
- The release of patient records and other information.
08.01.03 List of Abbreviations and Symbols

The ASC has a written policy and periodically updates a list of acceptable abbreviations and symbols for use in clinical records.
08.01.04 Authentication of Healthcare Record

The ASC has a **written** policy **addressing authentication of medical records approved by the medical staff that**:

- Requires every entry to be signed, or authenticated, by the healthcare professional making the entry.
- Complies with law and regulations.
- Identifies the portions of the medical record that may be delegated to a non-physician practitioner.
- Identifies the timeframe for physicians to authenticate medical record entries made by non-physician practitioners.
08.01.05 Documentation of Electronic Advice

The ASC has a **written policy approved by the medical staff** that a summary of any advice given to a patient by telephone or electronically, either during or after hours of operation, is

Establishes the triaging requirements for telephone calls.

Establishes any telephone advice given, either during or after hours of operation, requires a summary of that advice must be entered in the medical record.
Chapter 9
Patient Assessment and Discharge
No Significant Changes

- 09.00.00 Condition for Coverage: Patient Admission, Assessment, and Discharge (Current 13.00.01)
- 09.01.01 Intra-Operative Anesthesia Record (Current 03.03.03)
- 09.02.03 Patient Needs Identification (Current 07.01.02) *(Pieces of this standard moved to other standards)*
- 09.02.04 Assessment of Pain (Current 07.01.03)
- 09.02.06 Post-Surgical Needs Addressed in Discharge (Current 13.00.06)
- 09.03.01 Discharge Order (Current 13.00.08)
- 09.03.03 Discharge with a Responsible Adult (Current 13.00.09)
- 09.03.04 Patient Transfers (Current 07.01.05)
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:

(i) Include the time frame for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) 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)
§416.52(a)(1)(i)
§416.52(a)(1)(ii)
§416.52(a)(1)(iii)

The history and physical, if required, must be completed no more than 30 days prior to the date of a procedure.
09.00.02 Documentation of History and Physical (Current 13.00.03)

The patient’s medical history and physical examination (if any) must be placed in the patient’s medical record prior to the surgical procedure.

§416.52(a)(4)
09.00.03 Pre-Surgical Risk Assessment (Current 13.00.04)

Immediately before surgery:
- A physician must examine the patient to evaluate the risk of the procedure to be performed.  
  §416.42(a)(1)  
  §416.42(a)(1)(i)

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.  
The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.  
  §416.52(a)(2)  
  §416.52(a)(3)
09.00.04 Anesthetic Risk Assessment (Current 03.00.10)

Immediately before surgery:

- A physician must examine the patient to evaluate the risk of the procedure to be performed; and
- A physician or anesthetist as defined at 42 CFR § 410.69(b) must examine the patient to evaluate the risk of anesthesia.

§416.42(a)(l)
§416.42(a)(l)(i)
§416.42(a)(l)(ii)
09.02.01 Post-Surgical Assessment (Current 13.00.05)

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 the minimum, postoperative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

§ 416.52(b)(1)
Before discharge from the ASC, each patient must be evaluated by a physician or by 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, for proper anesthesia recovery.

§416.42(a)(2)
09.02.05 Identification and Response to Patient Deterioration (Current 07.01.04)

The ASC leadership has a policy approved by the medical staff that:

• Describes staff response upon recognition of patients with clinical deterioration
• Establishes the documentation expectations for the unstable patient including vital signs, treatments, medications, and patient response to treatments.
09.03.02 Discharge Instructions (Current 13.00.07)

The ASC must:

▪ 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 procedure or prior to leaving the ASC, of their prescriptions, postoperative instructions, and physician contact information for follow-up care.

§416.52(c)(1)
No Significant Changes

- 10.00.00 Condition for Coverage: Surgical Services (Current 03.00.01)
- 10.00.01 Surgical Procedures: Performed in a Safe Manner (Current 03.00.03)
- 10.00.02 Surgical Procedures: Performed by Qualified Physicians (Current 03.00.02)
- 10.01.03 Tissues Exempt from Pathological Examination (Current 03.01.04)
- 10.02.02 Circulating Nurse (Current 03.01.07)
10.00.03 Surgical Services Roster (Current 03.01.03)

Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each.
10.01.01 Surgical Procedures: Standardized Identification Process (Current 03.00.04)

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

The organization adopts written policies and procedures that include the use of standard procedures to ensure proper identification of the patient and procedural site to avoid wrong patient/wrong procedure/wrong site errors.
10.01.02 Operative Report (Current 03.03.05)

A dictated operative report, or written progress note is executed by the surgeon immediately after the procedure, describing:

- Techniques used.
- Findings.
- Tissues removed or altered.

Any implants placed during the procedure must be fully identified in the operative report.
10.01.04 Removed Specimens (NEW)

The organization has a written policy approved by the professional staff that identifies the storage, labeling, and transportation of specimens removed during a procedure and appropriate follow-up.
10.02.01 Adequate Staff (Current 03.01.08)

The ASC **leadership** ensures:

- Prior to the administration of general anesthesia, there is an adequate number of nursing/support staff (other than the anesthetists and surgeon) available to accommodate circulating and other similar duties.

- Staffing includes an adequate number of competent RNs to provide patient care in the PACU.
10.02.03 Surgical Procedures: Surgical Staff are Trained for Emergencies (Current 03.00.09)

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

The organization provides a safe environment by maintaining emergency equipment and training staff in its use.
10.03.01 Procedures Performed in the Appropriate Environment (Current 03.01.02)

The ASC leadership has written policies approved by the medical staff that defines for each location where invasive procedures are performed:

1. Invasive procedures must only be performed in an operating/procedure room unless another appropriate environment is identified by policy.
2. The type of procedure(s) that may be performed in each location.
3. Limitations on the complexity of procedures to be performed in any given procedure room.
4. The level of monitoring required for that procedure/location.
5. Minimum personnel requirements for that location/procedure.
6. If a room is not designated solely as an operating/procedure room, the policies must define what the room can be used for when surgery or other procedures are not taking place, and the cleaning and preparation required before a procedure can be done in that room and the post-procedure cleaning.
7. The process for the periodic review and amendment of procedures offered at the ASC.
10.03.02 Operating or Procedure Room Requirements (Current 03.00.06)

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

The organization ensures that the design of the operating or procedure room and provision of equipment and supplies are consistent with nationally recognized operating room/procedure room design and equipment guidelines.
Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

The organization must have a designated recovery area.
10.03.04 Surgical Procedures: Infection Prevention and Control Requirements (Current 03.00.08)

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

Operating and procedure rooms are maintained in accordance with nationally recognized guidelines.
10.03.05 Prevention of Surgical and Procedural Fires (Current 03.00.05)

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted privileges by the Governing Body of the ASC in accordance with approved policies and procedures of the ASC.

§416.42

The organization has written policies and procedures to prevent procedural fires.
The ASC leadership has a written policy approved by the medical staff that:

1. Establishes sufficient quantities and types of surgical instruments, supplies, and equipment, including appropriate automatic replenishment levels.

2. Addresses the requirement for supplies and equipment to be stored so that movement is minimized during cases.

3. Addresses the expectations for processed instruments to be protected from surface/airborne contamination.

4. Establishes the process to periodically use the input from staff to evaluate the quantity and quality of equipment available to meet the needs of the patients.
The ASC must determine the necessary supplies and equipment for emergency circumstances and maintain an adequate inventory of instrumentation, supplies and equipment.

At a minimum, the following equipment is available:

1. Communication/call-system.
2. Cardiac monitor.
3. Defibrillator, manual or AED.
4. Vacuum suction.
5. Ventilator, or manual ventilation assist device such as an Ambu bag.
6. As appropriate to the procedures performed and physician privileges:
   • Tracheotomy set.
   • Age/size specific.
   • Laryngoscope and endotracheal tubes.
10.03.08 Security of Supplies and Equipment (Current 03.02.04)

The ASC must implement adequate provisions to ensure the security of drugs, medical and dental devices, and medical gasses used for procedures.
10.04.01 Laser, Light-Based, and Other Energy-Emitting Technologies Officer (NEW)

An individual is designated to oversee education and safety for laser, light-based, and other energy-emitting technologies in use by the organization.
10.04.02 Laser, Light-Based, and Other Energy-Emitting Technologies Policies (NEW)

Policies are written to address the use and storage of laser, light-based, and other energy-emitting technologies in the organization.
10.04.03 Staffing for the Use of Laser, Light-Based, and Other Energy-Emitting Technologies (NEW)

Staff must have documentation of training for the use of each device. Non-credentialed staff must have approval to use each device in their position descriptions.
10.04.04 Warning Signs for Laser, Light-Based, and Other Energy-Emitting Technologies in Use (NEW)

Warning signs are prominently displayed at each entrance to the procedure room only when a device is in use.

Signage on the door states admission only by limits entry to authorized personnel.
10.04.05 Personal Protective Equipment for Laser, Light-Based, and Other Energy-Emitting Technologies in Use (NEW)

Personal protective equipment (PPE) is used for patients and staff.
10.04.06 Safety Features for Laser Procedures (Current 03.04.03)

The organization implements safety features for staff, patients, and the facility. A safety manual addressing each laser and light-emitting device is available to staff.

- The ASC must assure that there are patient and employee safety features such as:
  1. Protective equipment according to the manufacturer’s guidelines.
  2. Protective shields for any exposed areas as well as the eyes.
  3. Instruments that are non-reflective.
  4. Shields for windowed doors.
  5. Signage on the door that states admission only to authorized personnel.
  6. Fire extinguishers for electrical equipment.
  7. Sink and running water in the laser room.
  8. Peak performance calibration.
Standard Elimination

The following standards were incorporated into the newly revised standards and are no longer listed as individual:

- Standard 03.01.01 Approved Surgical Procedures
- Standard 03.04.01 Laser Procedures
- Standard 03.04.02 Laser Procedure Privileges
- Standard 03.04.04 Laser Procedures- QAPI
Chapter 11

Anesthesia Services
No Significant Changes

- 11.01.02 Administration of Anesthesia by Practitioners (Current 03.00.12)
- 11.01.06 Moderate Sedation Staffing Requirements (Current 03.01.06)
- 11.04.01 Adequate Anesthesia Equipment and Supplies (Current 03.02.01)
11.00.01 Anesthesia and Sedation Levels (NEW)

The organization identifies eligible anesthesia and sedation providers in accordance with the governing body’s approved scope of procedures and levels of anesthesia, sedation, and analgesia.
11.01.01 Director of Anesthesia Services (NEW)

The organization identifies a Director of Anesthesia Services and the responsibilities for the position.
11.01.03 Anesthesia and Sedation Administration (NEW)

The organization has a policy that limits the healthcare professional to performing the procedure and specifically identifies that the proceduralist may not administer any level of anesthesia or sedation.
11.01.04 Non-Anesthesia Professional Supervision of Moderation Sedation (Current 03.01.05)

The organization has policies for credentialing and granting privileges to qualified physicians who supervise moderate sedation by non-anesthesia professionals, in accordance with applicable regulations and professional scope of practice.

The ASC leadership has a policy approved by the medical staff that—

Defines “moderate sedation” consistent with generally accepted medical standards and enforces applicable standards of care for cases meeting this definition.
If the organization permits a registered nurse (RN) or other practitioner who is not an anesthesia professional to administer and monitor moderate sedation under the supervision of a physician with proper privileges, the organization must:

- Ensure that the administration of moderate sedation is in accordance with applicable laws and regulations and the RN or other practitioner’s scope of practice.
- Have a written job description detailing the roles and responsibilities, qualifications, and eligibility criteria for administering and monitoring moderate sedation.
- Ensure that the RN or other provider has documented training, experience, and evaluated competencies in administering moderate sedation inclusive of the pre-sedation, monitoring, and post-sedation evaluation of the patient response.
11.02.01 Policies, Procedures, and Protocols for Administering Moderate Sedation (NEW)

Policies, procedures, and protocols for administering moderate sedation include monitoring and evaluating the patient prior to, during, and after the procedure. A post-sedation evaluation prior to discharge is completed and documented.
11.03.01 Emergency Training (NEW)

Anesthesia providers and personnel have training in the emergency resuscitation care of the patient.
11.03.02 Malignant Hyperthermia Policy (Current 03.01.09)

If the ASC stocks malignant hyperthermia triggering agents provides general anesthesia, the ASC leadership has written policies and procedures approved by the medical staff that:

2. Identify the emergency medication required for treatment of malignant hyperthermia.
3. Require on-site availability of the emergency medications in the amounts required to rescue the patient.
11.04.02 Maintenance of Anesthesia Equipment (Current 03.02.03)

All anesthesia equipment must be maintained in compliance with all applicable requirements to conform to e.g., Safe Medical Devices/Food & Drug Administration requirements.

Anesthesia machines and related equipment undergo documented, routine preventive maintenance in accordance with manufacturer specifications or nationally recognized standards and guidelines. To include:

- Daily safety checks.
- At least quarterly preventive maintenance.
- Semi-annual waste gas analysis.
- At least semiannual electrical grounding/leakage/safety precautions.
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual:
  - Standard 03.03.01 Pre-Anesthesia Evaluation
  - Standard 03.03.03 Intra-operative/Anesthesia Record
Chapter 12
Pharmaceutical Services
No Significant Changes

- 12.00.01 Condition for Coverage: Pharmaceutical Services (Current 09.00.01)
- 12.01.01 Verbal Orders (Current 09.00.08)
- 12.01.02 Adverse Reactions (Current 09.00.06)
12.00.02 Compliance with Governmental Laws and Regulations (Current 09.01.01)

The ASC demonstrates compliance with requirements of the respective authority (e.g., State Board of Pharmacy).

The ASC’s pharmacy licenses are displayed, as required by law and regulations.
12.00.03 Drug and Biological Orders (Current 09.00.02)

Drugs must be prepared and administered according to established policies and acceptable standards of practice.

§416.48(a)

Qualified healthcare professionals order and supervise the administration of drugs and biologicals.
12.00.04 Labeling and Storage of Medications (Current 09.00.03)

Drugs must be prepared and administered according to established policies and acceptable standards of practice.

§416.48(a)

Drugs must be stored and labeled according to established policies and acceptable standards of practice.
12.00.05 Controlled Substances (Current 09.00.05)

Drugs must be prepared and administered according to established policies and acceptable standards of practice.

§416.48(a)

The organization has policies and procedures for managing the receipt, storage, and disposition of all controlled substances used.
12.00.06 Blood and Blood Products (Current 09.00.07)

Blood and blood products must be administered by only physicians or registered nurses.

§416.48(a)(2)
Drugs must be prepared and administered according to established policies and acceptable standards of practice.

§416.48(a)

The organization has policies and procedures supporting safe medication administration practices.
12.00.08 Preparation Area (NEW)

There is a designated area free of patients where medications, including multi-dose medications, if used, can be prepared for individual patients in the pre-op, operative, or recovery areas.
12.01.03 Medication Reconciliation (Current 09.01.02)

The organization has a process for medication reconciliation for each patient.

- The ASC has a process to document in the patient record a list of prescribed medications.
- For each medication, indicate, at least:
  - Drug name.
  - Dosage.
  - Indications for taking or using.
  - Frequency of usage.
12.02.01 Disposal of Drugs and Biologicals (NEW)

The organization has policies and procedures regarding the disposal of unused drugs and biologicals.
12.02.02 Security of Drugs and Biologicals (NEW)

Drugs and biologicals must be provided adequate security to prevent unauthorized access.
12.02.03 Emergency Drugs (Current 09.01.03)

The ASC has a policy approved by the medical staff that establishes:

▪ The emergency drugs and quantities to be maintained in the ASC.
▪ Emergency drugs in the ASC must be securely stored.
▪ A process to conduct and record an inventory of medications.
Chapter 13
Laboratory Services
No Significant Changes

- 13.00.00 Condition for Coverage: Laboratory Services (Current 10.00.01)
- 13.00.02 Laboratory Certification (Current 10.01.02)
- 13.03.01 PPM Laboratory Regulation Requirements (Current 10.01.04)
- 13.03.02 PPM Procedure Criteria (Current 10.01.03)
- 13.05.01 Contract Laboratory Services (Current 10.02.05)
- 13.06.01 Expired Supplies (Current 10.02.06)
13.00.01 Laboratory Services (Current 10.01.01)

If the ASC performs laboratory services, it must meet the requirements of 42 CFR 493. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with 42 CFR 493. 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 42 CFR 493.

§416.49(a)
13.01.01 Laboratory Director (Current 10.02.01)

All laboratory testing must be under the supervision of the current director who is identified on the CLIA certificate and must adhere to all relevant laws and regulations.
13.02.01 Waived Testing (Current 10.02.03)

Laboratories performing only waived testing have a current, valid CLIA Certificate of Waiver for each test or examination performed and categorized as waived by DHHS.
All personnel performing waived testing have appropriate training and demonstrate satisfactory levels of competence.

Such training and competency must be documented and a written policy and procedure must be in effect for such training.
13.02.03 Manufacturer’s Instructions for Waived Testing (NEW)

The laboratory maintains and follows a current copy of the manufacturer’s instructions for waived tests performed and follows the current manufacturer’s instructions.
13.02.04 Quality Control for Waived Tests (NEW)

The laboratory follows the manufacturer’s instructions for quality control (QC) and reviews the results to determine if results are acceptable prior to reporting patient results.

The laboratorydocuments corrective actions when QC results do not meet acceptable limits.
13.03.03 Certificate for PPM Procedures (NEW)

A valid CLIA Certificate for PPM Procedures is required for testing, and the organization or testing site must meet all applicable CLIA regulations including quality standards for moderate complexity testing.
13.03.04 PPM Director (NEW)

The laboratory director must be qualified to manage and direct laboratory personnel in the performance of PPM procedures.
13.03.05 PPM Personnel (NEW)

The organization must have a sufficient number of individuals qualified to perform the functions specified in this section based on the volume and complexity of testing performed.

There is a written program to ensure that each individual performing PPM procedures maintains satisfactory levels of competence.
The organization must have written policies/procedures for PPM procedures, as applicable, for:

- Each test performed, including specimen handling, performance, and reporting.
- Quality control (QC) for stains and reagents.
- Storage of reagents, test kits, and controls.
- Instrument maintenance and function checks (e.g., microscopes, centrifuges, etc.).
- Safety rules and regulations including, but not limited to, the use of personal protective equipment and adherence to universal precautions.
- Corrective action for QC failures.
13.04.01 Moderate or High Complexity Laboratories (Current 10.02.02)

Laboratories/Organizations performing moderate or high complexity testing must appropriately identify such tests and be certified under 42 CFR 493 Clinical Laboratory Improvement Amendments (CLIA) and have a current certificate of Compliance or Certificate of Accreditation from a program with deeming authority from the Department of Health and Human Services (DHHS).
13.06.02 Work Areas (NEW)

The work area for testing must be constructed, arranged, and maintained to ensure:

- Adequate space, ventilation, and utilities necessary for conducting all phases of the testing process.
- The potential for contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.
Standard Elimination

The following standards were incorporated into the newly revised standards and are no longer listed as individual:

- 10.02.07 Laboratory is Integrated with QAPI
Chapter 14
Radiologic Services
New Standard 14.00.00

- 14.00.00 Condition for Coverage: Radiologic Services
  Condition for Coverage: Radiologic Services.
  §416.49

- Required Elements:
  - Lack of substantial compliance with the radiologic services within this condition could provide a basis for citing a condition-level deficiency.
No Significant Changes

- 14.00.00 Condition for Coverage: Radiological Services (Current 10.00.01)
- 14.00.01 Radiological Services (Current 10.03.01)
- 14.01.01 Individual Responsible for Radiological Services (Current 10.03.02)
- 14.01.02 Orders for Radiologic Services (Current 10.03.07)
- 14.01.03 Retention of Records (Current 10.03.09)
- 14.01.04 Qualified Personnel (Current 10.03.08)
- 14.02.02 Shielding Safety (Current 10.03.04)
- 14.02.03 Radiation Exposure Monitoring (Current 10.03.06)
- 14.02.04 Periodic Inspection of Equipment (Current 10.03.05)
14.02.01 Safety for Patients and Personnel (Current 10.03.03)

Radiological services, particularly ionizing radiology, must be free from hazards for patients and personnel.

- Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials.

§482.26(b)
§482.26(b)(1)
14.02.05 Radioactive Materials (NEW)

The organization has written policies and procedures in place for receipt, storage, containment, and disposal of all radioactive materials including dyes, pharmaceuticals, and seeds.
Standard Elimination

- The following standards were incorporated into the newly revised standards and are no longer listed as individual:
  - 10.04.01 Contracted Radiological Services are Monitored
Thank you