

# State Operations Manual

## Appendix L - Guidance to Surveyors: Ambulatory Surgical Services - (Rev. 1, 05-21-04)

---

### §416.2 Definitions

§416.40 Condition for Coverage: Compliance With Licensure Law

§416.41 Condition for Coverage: Governing Body and Management

§416.41 Standard: Hospitalization

§416.42 Condition for Coverage: Surgical Services

§416.42(a) Standard: Anesthetic Risk and Evaluation

§416.42(b) Standard: Administration of Aesthesia

§416.42(c) Standard: Discharge

§416.43 Condition for Coverage: Evaluation of Quality

§416.44 Conditions for Coverage: Environment

§416.44(a) Standard: Physical Environment

§416.44(b) Standard: Safety From Fire

§416.44(c) Standard: Emergency Equipment

§416.44(d) Standard: Emergency Personnel

§416.45 Condition for Coverage: Medical Staff

§416.45(a) Standard: Membership and Clinical Privileges

§416.45(b) Standard: Reappraisals

§416.45(c) Standard: Other Practitioners

§416.46 Condition for Coverage: Nursing Service

§416.46(a) Standard: Organization and Staffing

§416.47 Condition for Coverage: Medical Records

§416.47(a) Standard: Organization

§416.47(b) Standard: Form and Content of Record

§416.48 Condition for Coverage: Pharmaceutical Services

§416.48(a) Standard: Administration of Drugs

§416.49 Condition for Coverage: Laboratory and Radiology Services

---

## §416.2 Definitions

**As used in this part; “Ambulatory surgical center” or “ASC” means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS under Medicare to participate as an ASC, and meets the conditions set forth in Subpart B and C of this part.**

### **Interpretive Guidelines §416.2**

The ASC must use its space for ambulatory surgery exclusively. Record keeping must be exclusive to the ASC, and the staff must be responsible to the ASC. For example, a nurse could not provide coverage in the ASC and in an adjacent clinic (or hospital) at the same time. The ASC is not required to be in a building separate from other health care activities (e.g., hospital, clinic, physician’s office). It must be separated physically by at least semi-permanent walls and doors.

The regulatory definition of an ASC does not allow the ASC and another entity to mix functions and operations in a common space during concurrent or overlapping hours of operation. Another entity may share **common space** only if the space is never used during the scheduled hours of ASC operation. However, the operating and recovery rooms must be used exclusively for surgical procedures.

The ASC may not perform a surgical procedure on a Medicare patient when, before surgery, an overnight hospital stay is anticipated. There may, however, arise unanticipated medical circumstances that warrant a Medicare patient’s hospitalization after an ASC surgical procedure. The ASC must have procedures for the immediate transfer of these patients to a hospital ([42 CFR §416.41](#)). Such situations should be infrequent.

ASC covered procedures (see [42 CFR §416.65](#)) are those that generally do not exceed 90 minutes in length and do not require more than four hours recovery or convalescent time. Thus, ASC patients generally do not require extended care as a result of ASC procedures. An unanticipated medical circumstance may arise that would require an ASC patient to stay in an overnight healthcare setting. Such situations should be infrequent. When extended care in a non-hospital healthcare setting is anticipated as a result of a particular procedure, that procedure would not be a covered ASC procedure for Medicare beneficiaries.

## **§416.40 Condition for Coverage: Compliance With Licensure Law**

**The ASC must comply with State licensure requirements.**

### **Interpretive Guidelines §416.40**

In States where licensure is required for a facility providing ambulatory surgical services, ask to see the facility's current license. If the State license is revoked, the ASC is out of compliance with this condition. This may result in its termination from participation in Medicare. Where a State has no applicable licensure requirements, or where ambulatory surgical services may be provided without licensure, a facility will be eligible if it meets the definition in [§416.2](#) and all other applicable Medicare requirements.

Failure of the facility to meet State licensure law may be cited when the authority having jurisdiction (AHJ) has made a determination of noncompliance and has also taken a final adverse action as a result. If the surveyor identifies a situation that indicates the provider may not be in compliance with State licensure law, the information may be referred to the AHJ for follow-up. If the facility is not in compliance with State licensure law, the facility could be found out of compliance with [§416.40](#).

---

## **Q-0003**

## **§416.41 Condition for Coverage: Governing Body and Management**

**The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. 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.**

### **Interpretive Guidelines §416.41**

The ASC must have a designated governing body that demonstrates its oversight of ASC activities intended to protect the health and safety of patients.

- An individual may act as the governing body in the case of sole-ownership, absentee ownership, or in other special cases.
- Responsibilities may be formally delegated to administrative, medical, or other personnel for carrying out various activities. However, the governing body must retain ultimate responsibility.

The ASC must establish and carry out activities that will ensure that contracted services are provided in a safe manner.

## **Survey Procedures and Probes §416.41**

Review chapter or titles of incorporation, bylaws, and partnership agreements. Annotate on the survey report form if full legal responsibilities have been established.

---

### **Q-0004**

#### **§416.41 Standard: Hospitalization**

**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. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment under [§482.2](#) of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.**

#### **Interpretive Guidelines §416.41**

An “effective procedure” encompasses:

- Written guidelines (e.g., policies and/or procedures);
- Arrangement for ambulance services; and
- Transfer of medical information.

## **Survey Procedures and Probes §416.41**

Request documentation of a transfer agreement or evidence of admitting privileges.

- Policies and procedures must be established for transferring patients requiring emergency care.
  - Appropriate personnel should be aware of transfer procedures.
- 

### **Q-0005**

#### **§416.42 Condition for Coverage: Surgical Services**

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

## **Interpretive Guidelines §416.42**

“In a safe manner” means that:

- The equipment and supplies are sufficient so that the type of surgery conducted can be performed in a manner that will not endanger the health and safety of the patient;
- Access to operative and recovery areas is limited;
- All individuals in the surgical area are to conform to aseptic techniques;
- Appropriate cleaning is completed between surgical cases;
- Suitable equipment is available for rapid and routine sterilization of operating room materials;
- Sterilized materials are packaged, labeled, and stored in a manner to ensure sterility and that each item is marked with the expiration date; and
- Operating room attire is suitable for the kind of surgical cases performed. (Persons working in the operating suite must wear clean surgical costumes in lieu of their ordinary clothing. Surgical costumes are to be designed for maximum skin and hair coverage.)

## **Survey Procedures and Probes §416.42**

Policies and procedures should contain at a minimum:

- Resuscitative techniques;
- Aseptic technique and scrub procedures;
- Care of surgical specimens;
- Appropriate protocols for all surgical procedures, specific or general in nature, and include a list of equipment, materials, and supplies necessary to properly carry out job assignments;
- Procedures addressing the cleaning of operating room after each use;
- Sterilization and disinfection procedures;
- Acceptable operating room attire;
- Care of anesthesia equipment; and

- Special provision for infected or contaminated patients.
- 

## **Q-0006**

### **§416.42(a) Standard: Anesthetic Risk and Evaluation**

**A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.**

#### **Survey Procedures and Probes §416.42(a)**

The medical record should confirm:

- If laboratory studies were ordered as part of patient evaluation. The report should be part of the medical record or notation of the findings recorded on the chart. For general anesthesia, the evaluation should contain, at a minimum, a brief note regarding the heart and lung findings the day of surgery; and
- Depending on the type of anesthesia and length of surgery, the postoperative check should include some or all of the following:
  - Level of activity;
  - Respirations;
  - Blood pressure;
  - Level of consciousness; and
  - Patient color.

---

## **Q-0007**

### **§416.42(b) Standard: Administration of Aesthesia**

**Anesthesia must be administered by only:**

**(1) A qualified anesthesiologist, or**

**(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist, a supervised trainee in an approved educational program, or an anesthesiologist's assistant. In those cases in which a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician,**

**and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.**

#### **Survey Procedures and Probes §416.42(b)**

The ASC indicates those persons qualified to administer anesthesia.

An approved educational program is a formal training program leading to licensure or certification in anesthesia that is recognized by the State.

---

### **Q-0008**

#### **§416.42(c) Standard: Discharge**

**All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.**

#### **Interpretive Guidelines §416.42(c)**

Any exceptions to this requirement must be made by the attending physician and annotated on the discharge plan.

---

### **Q-0009**

#### **§416.43 Condition for Coverage: Evaluation of Quality**

**The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.**

#### **Interpretive Guidelines §416.43**

Evaluation of quality of care is a rapidly evolving area. Major changes have occurred in the field of Quality Assurance, primarily in terminology and the methods used to monitor care. Some of the changes include:

- Increased emphasis on organizational systems and processes (rather than individual case review);
- Increased recognition of the need for objective data;
- Increased use of quality indicators or performance measures with which to analyze patient care processes and outcomes; and

- Increased emphasis on quality monitoring for identifying opportunities to improve care (rather than focusing only on problem identification).

Indicators or performance measures are tools that monitor important clinical, management, support, and governance processes and outcomes. Ongoing monitoring of important processes and outcomes allows the ASC to measure performance in key areas and identify opportunities to improve care.

### **Survey Procedures and Probes §416.43**

Items for discussion with facility staff may include:

- Describe an important opportunity to improve the patient care process or outcomes in the ASC;
- How did you become aware of this particular opportunity to improve patient care;
- What was done, or what would you suggest should be done, to improve the patient care process or outcome; and
- Who contributed, or who would you suggest contribute, to the improvement effort.

Items for review include:

- How and when is quality monitoring conducted;
- What key indicators of quality or performance measures are monitored by the ASC;
- How the medical staff participates in quality assurance;
- How appropriateness of care is reviewed; and
- How policies and clinical privileges are revised to improve patient care processes?

For an initial certification there are no historical records of quality monitoring to review. However, review for evidence that the ASC has outlined a program to monitor key indicators of quality and appropriateness, and that proper reporting and accountability mechanisms are in place. For existing programs, the most important factor to evaluate is whether the ASC's quality assurance or quality improvement program has been implemented. Review the facility's program documentation and other records to determine whether patient quality of care and administrative issues that impact on quality have been identified. The ASC should use the results of ongoing quality monitoring to



identify processes that need improvement, develop and implement corrective actions and evaluate whether the problems have been eliminated or minimized. Annotate on the survey report form what the ASC considers important processes to patient care that should be evaluated ongoing, and that are not ongoing. Ongoing means that there is continuing or periodic collection and assessment of data concerning all areas that impact on patient care. The program continually identifies processes for improvement and potential problems and indicates the data that should be collected and assessed in order to provide the ASC with routine findings regarding quality of patient care. The monitoring should be comprehensive and take into consideration medical necessity as it relates to the procedure performed by the ASC. The quality assurance or improvement program should also monitor the quality of patient education before procedures are performed and prior to discharge after the procedure. Specifically, are patients given necessary information to prepare for the procedure and to perform self-care and manage complications after discharge?

Evaluation of appropriateness of care should include analysis of:

- Anesthesia recovery;
- Infection rates;
- Pathology reports;
- Nursing services;
- Completeness of medical records;
- Complications that have occurred; and
- Stability at discharge.

There should be sufficient data in the medical records to support the diagnosis and procedures appropriate to the diagnosis. The methods use for facility self-assessment may be very flexible and there may be a wide variety of assessment techniques used. Care may be assessed prospectively, concurrently, or retrospectively. Where problems (or potential problems) are identified following the above analysis, ASCs should take appropriate action as soon as possible to avoid any risk to patients.

Examples of appropriate action may include:

- Changes in policies, processes and procedures;
- Staffing and assignment changes;
- Appropriate education and training;

- Adjustments in clinical privileges; and
  - Changes in equipment or physical plant.
- 

## **Q-0010**

### **§416.44 Conditions for Coverage: Environment**

**The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.**

#### **Survey Procedures and Probes §416.44**

Tour the facility and annotate on the survey report form whether the facility is adequately designed and equipped, clean and orderly, and free of hazards.

---

## **Q-0011**

### **§416.44(a) Standard: Physical Environment**

**The ASC must provide a functional and sanitary environment for the provision of surgical services.**

---

## **Q-0012**

**§416.44(a)(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.**

#### **Survey Procedures and Probes §416.44(a)**

Each operating room should be designed and equipped for the types of surgery performed and free of hazards to patients and staff (e.g., sufficient space, adequate lighting, necessary furniture).

---

## **Q-0013**

**§416.44(a)(2) The ASC must have a separate recovery room and waiting area.**

---

## **Q-0014**

**§416.44(a)(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.**

### **Interpretive Guidelines §416.44(a)(3)**

Since there is a risk of nosocomial infection there must be an active surveillance program of specific measures for prevention, early detection, control, education, and investigation of infectious and communicable diseases in ASCs. There must be a mechanism to evaluate the program(s) and take corrective action. The ASC should institute the most current recommendations of The Centers for Disease Control (CDC) and Prevention relative to the specific infection(s) and communicable disease(s).

### **Survey Procedures and Probes §416.44(a)(3)**

Annotate on the survey report form if the written policies and procedures do not contain, at a minimum:

- Methods to minimize sources and transmission of infection, including adequate surveillance techniques such as;
  - Assessing the risk for infections and communicable diseases;
  - Identifying patients at risk for infections and communicable diseases;
  - Educating health care workers about infectious and communicable diseases;
  - Screening health care workers;
  - Providing a safe environment consistent with the most current CDC recommendations;
  - Providing treatment measures consistent with the most current CDC recommendation for the identified infection and/or communicable disease; and
  - Providing for program evaluation and revision of program, when indicated.
- Sterilizing techniques for supplies and equipment;
- Procedures for isolation;
- Procedures for orientation of all new employees in infection control and personal hygiene; and
- Aseptic technique procedures.

Staff should have knowledge of infection control techniques and of the ASC's infection control program. The ASC should maintain an ongoing log that reports incidents of infection.

---

## **Q-0015**

### **§416.44(b) Standard: Safety From Fire**

**(1) Except as provided in paragraphs (b)(2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (NFPA) (which is incorporated by reference) that are applicable to ASCs.**

**(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the LSC 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.**

**(3) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the LSC, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues to remain in compliance with that edition of the LSC.**

#### **Interpretive Guidelines §416.44(b)**

The provisions of the NFPA (1985 edition) Life Safety Code, (unless facility is grandfathered under the 1981 LSC provisions prior to May 5, 1988) that apply are:

- Section 12-6 and Chapter 26, whichever provisions are more stringent, for new facilities and building permits issued or plans reviewed on or after May 5, 1988, (September 7, 1982, for facilities grandfathered under the 1981 LSC provisions);  
or
- Section 13-6 and Chapter 27, whichever provisions are more stringent, for facilities and building permits issued or plans reviewed prior to May 5, 1988, (September 7, 1982, for facilities grandfathered under the 1981 LSC provisions).

#### **Survey Procedures and Probes §416.44(b)**

The State fire authority should be used to conduct an LSC survey. This is usually the LSC unit of the State Health Department or the Office of the State Fire Marshal. It is the same unit that conducts LSC surveys for hospitals and nursing homes.

Whenever a waiver is requested, submit documentation of “unreasonable hardship” and “no adverse effects on health safety” along with your recommendations through the SA to the CMS Regional Office. The CMS Regional Office will grant or deny the waiver.

---

**Q-0016****§416.44(c) Standard: Emergency Equipment**

Emergency equipment available to the operating rooms must include at least the following:

---

**Q-0017**

**§416.44(c)(1) Emergency call system.**

**(2) Oxygen.**

**(3) Mechanical ventilatory assistance, equipment including airways, manual breathing bag, and ventilator.**

**(4) Cardiac defibrillator.**

**(5) Cardiac monitoring equipment.**

**(6) Tracheostomy s**

**(7) Laryngoscope and endotracheal tubes.**

**(8) Suction equipment.**

**(9) Emergency medical equipment and supplies specified by the medical staff.**

---

**Q-0018****§416.44(d) Standard: Emergency Personnel**

**Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.**

**Survey Procedures and Probes §416.44(d)**

Request documentation of personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation. Request documentation that indicates these personnel is available at all times for emergencies.

---

**Q-0019****§416.45 Condition for Coverage: Medical Staff**

**The medical staff of the ASC must be accountable to the governing body.**

**Interpretive Guidelines §416.45**

The organization of the medical staff is left to the discretion of the ASC governing body. (Membership on the governing body may include physician and non-physician practitioners.) Privileges granted, however, must be consistent with the license to practice in the State and the experience of each clinical practitioner.

---

**Q-0020****§416.45(a) Standard: Membership and Clinical Privileges**

**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 in accordance with recommendations from qualified medical personnel.**

**Interpretive Guidelines §416.45(a)**

The ASC is not required to follow each recommendation (e.g., acceptance or denial of privileges), but granting of privileges must be supported by recommendations.

**Survey Procedures and Probes §416.45(a)**

Select no more than five personnel records for medical staff members that have been granted clinical privileges and annotate on the survey report form if there is no documentation of personnel qualifications, privileges granted, appropriate records and other related documents.

---

**Q-0021****§416.45(b) Standard: Reappraisals**

**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.**

## **Survey Procedures and Probes §416.45(b)**

The policies and procedures manuals should state how often reappraisals are to be conducted.

Select no more than five personnel records for medical staff members that have been granted clinical privileges and annotate on the survey report form if there is no documentation of reappraisals being performed timely.

---

### **Q-0022**

#### **§416.45(c) Standard: Other Practitioners**

**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.**

#### **Interpretive Guidelines §416.45(c)**

Patient care responsibilities (which may or may not include formal privileges) may be assigned to practitioners not meeting the definition of physician in §1861(r) of the Act. However, policies and procedures must be established (e.g., either as part of overall medical staff bylaws or as separate documents) to oversee their clinical activities.

“Physician” is defined in [§1861\(r\)](#) of the Social Security Act as:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry with respect to services legally authorized to be performed in the State; and
- Chiropractor with respect to treatment by manual manipulation of the spine (to correct subluxation diagnosed by x-ray).

All of the above must practice in accordance with State licensure.

---

### **Q-0023**

#### **§416.46 Condition for Coverage: Nursing Service**

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

---

**Q-0024****§416.46(a) Standard: Organization and Staffing**

**Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.**

**Interpretive Guidelines §416.46(a)**

“Available” means on the premises and sufficiently free from other duties, enabling the individual to respond rapidly to emergency situations. Functions, qualifications, and patient care responsibilities should be delineated for all nursing personnel.

**Survey Procedures and Probes §416.46(a)**

Select a random sample of surgical cases. Annotate on the survey report form if registered nurses are not onsite and available for emergencies during ASC hours of operation. ASC policy must explain current acceptable standards of practice. “Recognized standards of practice” are standards promoted by national, State, and local nursing associations, relating to safe and effective nursing services.

---

**Q-0025****§416.47 Condition for Coverage: Medical Records**

**The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.**

**Survey Procedures and Probes §416.47**

Medical records should be properly indexed and readily retrievable. Make sure that medical records are protected from fire and unauthorized access, and are properly stored. The policy manual must address retention, preservation, and confidentiality of the medical records

---

**Q-0026****§416.47(a) Standard: Organization**

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



### **Survey Procedures and Probes §416.47(a)**

If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form. Request six patient records and observe whether the facility has a functioning medical record system that safeguards the retention of medical records.

---

### **Q-0027**

### **§416.47(b) Standard: Form and Content of Record**

**The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:**

### **Survey Procedures and Probes §416.47(a)**

Select a random sample of records to evaluate the completeness of information, recording of treatment/services provided, and content as specified in this standard. The random sample should include a sample of records from all practitioners. If you identify specific problems or trends of incomplete records, select additional records.

---

### **Q-0028**

#### **§416.47(b)(1) Patient identification;**

- (2) Significant medical history and results of physical examination;**
- (3) Pre-operative diagnostic studies (entered before surgery), if performed;**
- (4) Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;**
- (5) Any allergies and abnormal drug reactions;**
- (6) Entries related to anesthesia administration;**
- (7) Documentation of properly executed informed patient consent;**
- (8) Discharge diagnosis.**

### **Survey Procedures and Probes §416.47(b)(2)**

The medical history and physical examination should be relevant to the reason for surgery and the type of anesthesia planned. It should validate the need for surgery balanced against the risk factors associated with anesthesia (e.g., smoking history,

problems associated with past anesthesia). Record any inconsistencies on the survey report form.

### **Survey Procedures and Probes §416.47(b)(4)**

Request the list of approved exemptions. Exemptions to a pathology report should be made only when the quality of care is not compromised by the exemption and when another suitable means of verification of removal is employed. In these cases, the authenticated operative report must document the removal. Exceptions to sending specimens to the pathologist for evaluation could be made for such limited categories as foreign bodies, teeth, or other specimens that by their nature or condition do not permit fruitful examination.

Request the list of exemptions that have been approved by the governing body. Annotate on the survey report form if these exemptions appear inappropriate.

Select five medical records and annotate whether the exemptions contained therein are consistent with those exemptions previously approved.

---

## **Q-0029**

### **§416.48 Condition for Coverage: Pharmaceutical Services**

**The ASC 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.**

#### **Interpretive Guidelines §416.48**

“Accepted professional practice” and “acceptable standards of practice” mean patient care standards established by national, State, and local professional associations regarding clinical use of drugs and biologicals.

There should be records of receipt and disposition of all controlled drugs.

The label of drug containers should have the name, strength, directions for use and expiration date of the drug.

#### **Survey Procedures and Probes §416.48**

Record whether there are procedures for disposal of discontinued, outdated, and deteriorated drugs. Drugs and biologicals must be current, not outdated, and properly refrigerated, if necessary.

Annotate on the survey report form if no one is designated the responsibilities for pharmaceutical services.

---

**Q-0030****§416.48(a) Standard: Administration of Drugs**

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

---

**Q-0031**

**§416.48(a)(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.**

**Survey Procedures and Probes §416.48(a)(1)**

The ASC must have policies and procedures in place covering the administration and preparation of drugs and reporting of adverse drug reactions.

Request five patient records and note if the procedures are being followed.

---

**Q-0032**

**§416.48(a)(2) Blood and blood products must be administered only by physicians or registered nurses.**

**Survey Procedures and Probes §416.48(a)(2)**

The ASC must have policies and procedures that identify who is authorized to administer blood and blood products.

---

**Q-0033**

**§416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.**

**Survey Procedures and Probes §416.48(a)(3)**

Record whether medication orders are signed by the physician.

Select five medication cards and annotate on the survey report form if they confirm the physician's order, i.e., that drug, dosage, and administration are as directed.

---

## Q-0034

### **§416.49 Condition for Coverage: Laboratory and Radiology Services**

**If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. 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 part 493 of this chapter. 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. The ASC must have procedures for obtaining radiology services, from a Medicare approved facility to meet the needs of patients.**

#### **Interpretive Guidelines §416.49**

ASC policies and procedures should list the kinds of laboratory services that are provided directly by the facility, and services that are provided through a contractual agreement. Review the contractual agreements and determine if the referral laboratory is a CLIA-approved laboratory. Policies and procedures should encompass the following:

- A well-defined arrangement (need not be contractual) with outside services;
- Laboratory services that are provided by the ASC;
- Routinized procedures for requesting lab tests and radiological exams; and
- Incorporate lab/radiological reports into patient records.

When laboratory tests are performed prior to admission, the results should be readily available to the attending physician in the ASC.

If the facility provides directly for all radiological services, the surveyor is to apply either the Condition of Participation for Hospitals at [§482.26](#) - Radiology Department, or the Conditions for Coverage of portable x-ray services at [§§405.1411-405.1416](#). If the services are provided for other than patients of the ASC, the facility could not be certified as an ASC. (See [§416.2](#), Definition.)

When the ASC fails to meet either the radiology requirement for hospitals or portable x-ray requirement, then all radiology services must be obtained from a Medicare- approved facility. Note, however, that a Medicare-approved portable x-ray supplier is not a facility and cannot provide x-ray services to an ASC. Portable x-ray services must be furnished in a place of residence used as the patient's home (as detailed in [42 CFR 410.32\(a\)\(2\)](#)).