

Medicare Conditions of Coverage Comparison of Existing Regulations to Regulations Effective May 18, 2009

Existing regulatory language is in black text. Finalized deletions are lined through and in color. Additions are underlined and in color.

NOTE: This comparison was prepared for sole purpose of enabling ASC Association members to identify how the regulations are changing.

Subpart A—General Provisions and Definitions

§ 416.1 Basis and scope.

(a) Statutory basis.

(1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) Scope. This part sets forth —

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility 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, and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have ~~has~~ an agreement with CMS to participate in Medicare as an ASC, and must meet ~~meets~~ the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by CMS in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

Subpart B—General Conditions and Requirements

§ 416.25 Basic requirements.

Participation as an ASC is limited to facilities that —

(a) Meet the definition in § 416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

§ 416.26 Qualifying for an agreement.

(a) Deemed compliance. CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) Survey of ASCs. (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) Acceptance of the ASC as qualified to furnish ambulatory surgical services. If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) Filing of agreement by the ASC. If the ASC wishes to participate in the program, it must —

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) Acceptance by CMS. If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) Appeal rights. If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

§ 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) Compliance with coverage conditions. The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) Limitation on charges to beneficiaries.¹ The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary —

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(c) Refunds to beneficiaries. (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, money incorrectly collected means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

(d) Furnishing information. The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) Acceptance of assignment. The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under §424.64 of this chapter (when an individual dies before assigning the claim).

(f) ASCs operated by a hospital. In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless CMS determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report.

(g) Additional provisions. The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

§ 416.35 Termination of agreement.

(a) Termination by the ASC—

¹ For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(1) Notice to CMS. An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) Date of termination. The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) Voluntary termination. If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) Termination by CMS — (1) Cause for termination. CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) Notice of termination. CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) Appeal by the ASC. An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) Effect of termination. Payment is not available for ASC services furnished on or after the effective date of termination.

(d) Notice to the public. Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) Conditions for reinstatement after termination of agreement by CMS. When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

Subpart C—Specific Conditions for Coverage

§ 416.40 Condition for coverage— Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§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. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures ensuring that facility these policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

(a) Standard: Contract services. 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.

(b) Standard: Hospitalization. (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 this chapter.

(3) The ASC must—

(i) Have a written transfer agreement with ~~such~~ a hospital that meets the requirements of paragraph (b)(2) of this section; or

(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at ~~such~~ a hospital that meets the requirements of paragraph (b)(2) of this section.

(c) Standard: Disaster preparedness plan. (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.

(2) The ASC coordinates the plan with State and local authorities, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

§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.

(a) Standard: Anesthetic risk and evaluation. (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

(b) Standard: Administration of anesthesia. Anesthetics must be administered by only —

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph [(c)] of this section, 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.²

~~(c) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.³~~

~~(c)-(d) Standard: State exemption. (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality~~

² Editors note: Prior to revision, when § 416.42(b)(2) of the ASC Conditions for Coverage discussed exemptions to the requirement that non-physicians be supervised when administering anesthesia it made reference to "paragraph (d) of this section," which corresponded to a paragraph entitled "Standard: State exemption" When the Conditions for Coverage were revised this paragraph "Standard: State exemption" was re-designated as paragraph (c) of §416.42. However, the above mentioned reference in § 416.42(b)(2) to "paragraph (d) of this section" was not changed. Because, in the revised Conditions for Coverage there is not a paragraph (d) in §416.42, and because the re-designated paragraph (c), as it was the old paragraph (d), addresses state exemptions to the requirement to supervise non-physicians when they administer anesthesia, failure to change "paragraph (d) of this section" to "paragraph (c) of this section" was surely an oversight by CMS. Thus, we have taken the liberty of changing "paragraph (d) of this section" to "paragraph (c) of this section" in this redline version.

³ Editor's note: The language "All patients are discharged in the company of a responsible adult, except those exempted by the attending physician" deleted from section "Standard: Discharge" (§416.42(c)) has been incorporated into the to the newly added §416.52 (c)(3), which reads: "Ensure *all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.*" (emphasis supplied).

of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

§416.43 Conditions for coverage—Quality assessment and performance improvement.

~~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. develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.~~

~~(a) Standard: Program scope. (1) 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.~~

~~(2) 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.~~

~~(b) Standard: Program data. (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.~~

~~(2) The ASC must use the data collected to—~~

~~(i) Monitor the effectiveness and safety of its services, and quality of its care.~~

~~(ii) Identify opportunities that could lead to improvements and changes in its patient care.~~

~~(c) Standard: Program activities. (1) The ASC must set priorities for its performance improvement activities that—~~

~~(i) Focus on high risk, high volume, and problem-prone areas.~~

~~(ii) Consider incidence, prevalence, and severity of problems in those areas.~~

~~(iii) Affect health outcomes, patient safety, and quality of care.~~

~~(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.~~

~~(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.~~

~~(d) Standard: Performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.~~

~~(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.~~

~~(e) Standard: Governing body responsibilities. 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.~~

§ 416.44 Condition 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.

(a) Standard: Physical environment. The ASC must provide a functional and sanitary environment for the provision of surgical services. (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.

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

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

(b) Standard: Safety from fire. (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101 @ 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

<http://www.archives.gov/federalregister/codof/federalregulations/ibrlocations.html>. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(c) Standard: Emergency equipment. Emergency equipment available to the operating rooms must include at least the following:

(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 set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

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

(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.

§ 416.45 Condition for coverage—Medical staff.

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

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

(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.

(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.

§ 416.46 Condition for coverage—Nursing services.

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

(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.

§ 416.47 Condition for coverage—Medical records.

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

(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(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:

- (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.

§ 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.

(a) Standard: Administration of drugs. Drugs must be prepared and administered according to established policies and acceptable standards of practice.

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

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

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

§416.49 Condition for coverage—Laboratory and radiologic services.

(a) Standard: Laboratory 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.

(b) Standard: Radiologic services. (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in §482.26 of this chapter.

§416.50 Condition for coverage—Patient rights.

The ASC must inform the patient or the patient’s representative of the patient’s rights, and must protect and promote the exercise of such rights.

(a) Standard: Notice of rights. (1) The ASC must provide the patient or the patient’s representative with verbal and written notice of the patient’s rights in advance of the date of the procedure, in a language and manner that the patient or the patient’s representative understands. In addition, the ASC must—

(i) Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. The ASC’s notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(ii) The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.

(2) Standard: Advance directives. The ASC must comply with the following requirements:

(i) Provide the patient or, as appropriate, the patient’s representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(ii) Inform the patient or, as appropriate, the patient’s representative of the patient’s right to make informed decisions regarding the patient’s care.

(iii) Document in a prominent part of the patient’s current medical record, whether or not the individual has executed an advance directive.

(3) Standard: Submission and investigation of grievances. (i) 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.

(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC.

(iv) Only substantiated allegations must be reported to the State authority or the local authority, or both.

(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient’s representative regarding treatment or care that is (or fails to be) furnished.

(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

(b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to—

(i) Exercise his or her rights without being subjected to discrimination or reprisal.

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

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

(2) If a patient is adjudged incompetent under applicable State health and safety 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.

(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient’s rights to the extent allowed by State law.

(c) Standard: Privacy and safety. The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) Standard: Confidentiality of clinical records. The ASC must comply with the Department’s rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

§416.51 Conditions for coverage—Infection control.

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

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

(b) Standard: Infection control program. 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. The program is—

- (1) Under the direction of a designated and qualified professional who has training in infection control;
- (2) An integral part of the ASC’s quality assessment and performance improvement program; and
- (3) 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.

§416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

(a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient’s condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.

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

(b) Standard: Post-surgical assessment. (1) The patient’s post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) Standard: Discharge. The ASC must—

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup 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, post-operative instructions and physician contact information for followup care.

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.⁴

⁴ Editor’s Note: § 416.52(c)(3)’s requirement that “all patients are discharged in the company of a responsible adult, except those exempted by the attending physician” was, prior to revision, part of §416.42 (c) . During revision § 416.42(c) was deleted and the language “all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician” was incorporated in to the newly created § 416.52(c)(3).