
CMS Manual System

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Centers for Medicare &
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(CMS)

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Date: March 27, 2015

SUBJECT: Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Beds

I. SUMMARY OF CHANGES: We are revising the following appendices to reflect recent regulation changes: Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Appendix G, Guidance to Surveyors Rural Health Clinics, Appendix L, Guidance for Surveyors Ambulatory Surgical Centers, and Appendix T, Regulations and Interpretive Guidelines for Swing Beds in Hospitals. We are taking this opportunity to make clarifications and updates to existing guidance.

NOTE: We are also revising the Table of Contents for Appendices A, G, and L by removing reference to the standards and only listing the conditions. Standard level Tags were added for the Condition-level statements in Appendix A and Appendix L: Tag A-1081 is new, the Interpretive Guidelines have been relocated from Tag A-1080; Tag Q-0064 is new, the Interpretive Guidelines have been relocated from Tag Q-0060. Finally, as seen in Appendix T, the regulation governing Swing Bed services was moved from §482.66 to §482.58.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: March 27, 2015
IMPLEMENTATION DATE: March 27, 2015**

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS:)
(R = REVISED, N = NEW, D = DELETED)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A Table of Contents
D	Appendix A/A-0628/§482.28(b) Standard: Diets
R	Appendix A/A-0629§482.28(b) Menus must meet the needs of patients.
R	Appendix A/ A-0630
R	Appendix A/A-0652 §482.30 Condition of Participation: Utilization Review

R	Appendix A/A-0653/§482.30(a) Standard: Applicability
R	Appendix A/A-0658 §482.30(f) Standard: Review of Professional Services
R	Appendix A/A-1036
R	Appendix A/A-1076 §482.54 Condition of Participation: Outpatient Services
R	Appendix A/A-1080/§482.54(c) Standard: Orders for Outpatient Services
N	Appendix A/A-1081 §482.54 Standard Level Tag for Outpatient Services Condition
R	Appendix A/A-1132 §482.56(b) Standard: Delivery of Services
R	Appendix A/1-1163
R	Appendix G/Table of Contents
R	Appendix G/§491.8 Condition for Certification: Staffing and Staff Responsibilities
R	Appendix L/Table of Contents
R	Appendix L/ Q-0042 §416.41(b) Standard: Hospitalization
R	Appendix L/ Q-0060 §416.42 Condition for Coverage: Surgical Services
N	Appendix L/ Q-0064 §416.42 Standard level tag for Condition for Coverage: Surgical Services
R	Appendix L/Q-0101 §416.44(a)(1) Standard: Physical Environment
R	Appendix L/ Q-0122 §416.45(b) Standard: Reappraisals
R	Appendix L/ Q-0202/ §416.49(b)(1) Standard: Radiologic Services
N	Appendix L/ Q-0203/§416.49(b)(1) [Radiologic services...] must meet the requirements specified in §482.26(b), (c)(2), and (d)(2) of this chapter.
N	Appendix L/ Q-0204/§416.9(b)(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.
R	Appendix L/ Q-0221/ §416.50(a) Standard: Notice of Rights
R	Appendix L/ Q-0222/ §416.50(a)(1)(i) [...] In addition, the ASC must – (i)Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, 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.
R	Appendix L/ Q-0229/ §416.50(e)(1)(iii) Standard: Exercise of rights and respect for property and person. [(1) The patient has the right to the following:]

	(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.
R	Appendix L/Q-0266/ §416.52(c)(2) Standard: Discharge. The ASC must - (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.
R	Appendix T Table of Contents
R	Appendix T/A-1500/§482.58 Special Requirements for Hospital Providers of Long-Term Care Services (“Swing-Beds”)
R	Appendix T/A-1501/§482.58(a)(1) – (4) Eligibility
D	Appendix T/A-1502/§482.58(a)(2)
D	Appendix T/A-1503/§482.58(a)(3)
D	Appendix T/A-1504/§482.58(a)(4)
R	Appendix T/A-1505/§482.58(b) Skilled Nursing Facility Services

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev.136, Issued: 03-27-15)

Transmittals for Appendix A

Survey Protocol

Introduction

Task 1 - Off-Site Survey Preparation

Task 2 - Entrance Activities

Task 3 - Information Gathering/Investigation

Task 4 - Preliminary Decision Making and Analysis of Findings

Task 5 - Exit Conference

Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

§482.11 Condition of Participation: Compliance with Federal, State and Local Laws

§482.12 Condition of Participation: Governing Body

§482.13 Condition of Participation: Patient's Rights

***§482.21 Condition of Participation: Quality Assessment and Performance
Improvement Program***

§482.22 Condition of Participation: Medical staff

§482.23 Condition of Participation: Nursing Services

§482.24 Condition of Participation: Medical Record Services

§482.25 Condition of Participation: Pharmaceutical Services

§482.26 Condition of Participation: Radiologic Services

§482.27 Condition of Participation: Laboratory Services

§482.28 Condition of Participation: Food and Dietetic Services

§482.30 Condition of Participation: Utilization Review

§482.41 Condition of Participation: Physical Environment

§482.42 Condition of Participation: Infection Control

§482.43 Condition of Participation: Discharge Planning

§482.45 Condition of Participation: Organ, Tissue and Eye Procurement

§482.51 Condition of Participation: Surgical Services

§482.52 Condition of Participation: Anesthesia Services

§482.53 Condition of Participation: Nuclear Medicine Services

§482.54 Condition of Participation: Outpatient Services

§482.55 Condition of Participation: Emergency Services

§482.56 Condition of Participation: Rehabilitation Services

§482.57 Condition of Participation: Respiratory Services

A-0629

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.28(b) Menus must meet the needs of patients.

(1) - *Individual patient nutritional needs must be met in accordance with recognized dietary practices.*

Interpretive Guidelines §482.28(b)(1)

Each hospital patient for whom the hospital is providing one or more meals or nutrition must have their nutritional needs met in a manner that is consistent with recognized dietary practices. Affected patients include all inpatients and those patients in outpatient status, including the provision of observation services, whose stay is sufficiently long that they must be fed. According to the U.S. Department of Agriculture's (USDA) Food and Nutrition Center the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board's Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings. The DRIs are a set of four reference values:

- Recommended Dietary Allowance (RDA) is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.*
- Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) and is only established when an RDA cannot be determined. Therefore a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.*
- Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.*
- Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the population.*

USDA provides access to an interactive DRI tool and DRI tables at <http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes>

Meeting individual patient nutritional needs may include the use of therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

Patients must be assessed for their risk for nutritional deficiencies or need for therapeutic diets and/or other nutritional supplementation.

Examples of patients who may have specialized dietary needs and may require a more detailed nutritional assessment include, but are not limited to:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);*
- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;*
- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.);*
- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).*

Patients who refuse the food served should be offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs.

The care plan for patients identified as having specialized nutritional needs must address those needs as well as monitoring of their dietary intake and nutritional status. The methods and frequency of monitoring could include one or more of the following, as well as other methods:

- Patient weight (BMI, unintended weight loss or gain)*
- Intake and output*
- Lab values*

Survey Procedures §482.28(b)(1)

- Can the dietician demonstrate how the menus meet the nutritional needs of patients. For example, does the service rely upon DRIs, including RDAs, in developing menus?*
- Can the dietician demonstrate patients are assessed for special nutritional needs and how the hospital assures the needs of those with specialized needs are met?*
- When observing care in inpatient units (or observation units where meals are provided) ask staff how patients are assessed for nutritional needs.*
 - Ask them how they monitor patients identified as having specialized needs.*
 - Is there evidence that therapeutic diets are provided as ordered?*

- *Does the sample of patient records being reviewed include patients identified with special nutritional needs? If not, ask to see records for several such patients. Determine if there is evidence of monitoring the dietary intake and nutritional status of patients identified as having special nutritional needs.*

A-0630

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§482.28(b)(2) - *All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.*

Interpretive Guidelines §482.28(b)(2)

Patient diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional who is permitted to order diets under State law and authorized to do so by the medical staff.

Diets must be based on an assessment of the patient's nutritional and therapeutic needs and documented in the patient's medical record (including documentation about the patient's tolerance to any therapeutic diet ordered).

The hospital's governing body may choose, when permitted under State law and upon recommendation of the medical staff, to grant qualified dietitians or qualified nutrition professionals diet-ordering privileges. In many cases State law determines what criteria an individual must satisfy in order to be a "qualified dietician;" State law may define the term to mean a "registered dietician" registered with a private organization, such as the Commission on Dietetic Registration, or State law may impose different or additional requirements. Terms such as "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" are also used to refer to individuals who are not dietitians, but who may also be qualified under State law to order patient diets. It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them privileges to order diets.

If the hospital chooses not to grant diet-ordering privileges to dietitians or other nutrition professionals, even when permitted under State law, the patient's diet must be prescribed by a practitioner responsible for the patient's care. In this situation, a dietitian or nutrition professional who does not have privileges to order diets may nevertheless assess a patient's nutritional needs and provide recommendations or consultations for patients to a practitioner responsible for the care of the patient.

Survey Procedures §482.28(b)(2)

- Review patient records to verify that diet orders are provided as prescribed by the practitioner(s) responsible for the care of the patient, *a qualified dietitian, or qualified nutrition professional.*
- *If diet orders are prescribed by a dietitian or other nutrition professional, review their records to verify that he or she was appointed to the medical staff with diet-ordering privileges, or was granted diet-ordering privileges without being appointed to the medical staff.*
- *Ask the hospital how it determines whether the dietician/nutrition professional is qualified under state law. Review staff records to verify that dietitians/nutrition professionals demonstrate the required qualifications.*

A-0652

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§482.30 Condition of Participation: Utilization Review

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

Interpretive Guidelines §482.30

If the hospital does not satisfy one of the exception criteria at §482.30(a), it must have a UR plan in effect *which provides for review of services provided to Medicare and Medicaid beneficiaries.*

Survey Procedures §482.30

The manner and degree of noncompliance with one or more of the UR standards is considered when determining whether there is condition-level compliance or non-compliance.

A-0653

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§482.30(a) Standard: Applicability

The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.

Interpretive Guidelines §482.30(a)

The regulation permits two exceptions to the requirement for a hospital UR plan: (1) where the hospital has an agreement with a QIO under contract with the Secretary to assume binding review for the hospital or; (2) where CMS has determined that UR procedures established by the State under Medicaid are superior to the UR requirements for the Medicare program and has required hospitals in that State to meet the UR requirements for the Medicaid program at 42 CFR 456.50 through 456.245.

According to the regulation at 42 CFR 476.86(e), QIO review and monitoring activities fulfill the requirements for compliance activities of State Survey Agencies under §1861(k) of the Social Security Act (Act). The statutory requirements for utilization review at §1861(k) of the Act are reiterated in the UR CoP at 42 CFR 482.30. Therefore, a hospital meets the exception requirements of 42 CFR 482.30 if a QIO has assumed binding review for the hospital. (The hospital may not make requests for work to be performed by the QIO that goes beyond the scope of the QIO's contract with the Secretary.)

The regulation at 42 CFR 489.20(e) requires a hospital to maintain an agreement with a QIO to review the admissions, quality, appropriateness, and diagnostic information related to inpatient services for Medicare patients, if there is a QIO with a contract with CMS in the area where the hospital is located.

CMS anticipates that most hospitals comply with the UR CoP by means of the QIO exception.

With regard to the second exception, CMS would have to determine that UR procedures established by a State under Medicaid are superior to the UR requirements for Medicare. Currently no UR plans established by a State under Medicaid have been approved as exceeding the requirements under Medicare and required for hospital compliance with the Medicare UR CoP within that State. In the event that CMS approves a State's Medicaid UR process for compliance with the Medicare UR CoP, CMS will advise the affected State Survey Agency.

Survey Procedures §482.30(a)

Surveyors are to verify either that the hospital:

- Has its own UR plan in place and that it meets the regulatory requirements; or
- If it does not have its own UR plan, that it has an agreement with the QIO that provides for binding UR review. Surveyors should ask to see the signed, dated agreement. *If the hospital has an agreement with a QIO, it is not necessary for surveyors to assess the remaining UR standards.*

It is not necessary for SAs to conduct routine surveys for compliance with the provider agreement requirement to have a QIO agreement. However, a hospital that does not satisfy the UR CoP through either its own program or a QIO agreement may be cited for violating the UR CoP at the condition level.

A-0658

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§482.30(f) Standard: Review of Professional Services

The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

Interpretive Guidelines §482.30(f)

“Professional” services *means the services provided by practitioners, including both physicians and non-physician practitioners.*

The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are:

- Availability and use of necessary services - underused, overuse, appropriate use
- Timeliness of scheduling of services - operating room, diagnostic
- Therapeutic procedures

Survey Procedures §482.30(f)

Determine that the committee performs a review of professional services.

A-1036

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.53(b)(1) In-house preparation of radio pharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

Interpretive Guidelines §482.53(b)(1)

If the hospital prepares radio pharmaceuticals in-house, *such* preparation must be performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law. *Hospitals must establish policies and procedures*

for in-house preparation of radiopharmaceuticals, including by nuclear medicine technologists under supervision.

The policies and procedures must identify the qualifications, roles and responsibilities of staff preparing radiopharmaceuticals under supervision. The hospital must ensure that all staff who are involved in the preparation and/or supervision of radiopharmaceuticals are trained and demonstrate competencies in accordance with acceptable standards of practice.

Hospitals are expected to develop policies and procedures with respect to supervision of nuclear medicine technologists. CMS anticipates that most hospitals will follow the supervision recommendations of the Society of Nuclear Medicine and Molecular Imaging, but there is no mandate that every hospital does so. (79 FR 27120, May 12, 2014) Recommendations are available at: <http://www.snmmi.org/files/docs/NMT%20SOP%20Clinical%20Performance%20Standards%20June%202013.pdf> If a hospital is not following this guidance, then it must be able to explain the basis for the supervision policies and procedures it has developed.

Survey Procedures §482.53(b)(1)

- If radio pharmaceuticals are prepared in-house, determine that the preparation is performed by, or supervised by, a registered pharmacist or MD/DO.
- *Review personnel records of pharmacists, MDs/DOs and nuclear medicine personnel involved in the preparation and supervision of radio pharmaceuticals to verify they have required qualifications per State law and hospital policy.*
- *Verify that the hospital has policies regarding the supervision of nuclear medicine personnel and the in-house preparation of radio pharmaceuticals.*
- *Ask the supervising pharmacist or MD/DO how technicians who prepare radio pharmaceuticals are supervised. Are the supervision policies based on the recommendations of the Society of Nuclear Medicine and Molecular Imaging? If not, what is the basis for the supervision policies?*
 - *Ask what policies/procedures the hospital uses to assure proper preparation.*
 - *Ask what guidelines the hospital relies upon for radio pharmaceutical preparation.*

A-1076

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.54 Condition of Participation: Outpatient Services

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.54

This is an optional hospital service; however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP).

The Medicare Hospital CoP applies to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations.

Tag *A-108I* permits standard-level citations for identified deficiencies and provides more detailed guidance on the overall requirements for outpatient services.

The manner and degree of noncompliance identified in relation to Tags 1077 – 1080 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

A-1080

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.54(c) Standard: Orders for Outpatient Services

Outpatient services must be ordered by a practitioner who meets the following conditions:

- (1) Is responsible for the care of the patient.*
- (2) Is licensed in the State where he or she provides care to the patient.*
- (3) Is acting within his or her scope of practice under State law.*
- (4) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services.*

This applies to the following:

(i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.

Interpretive Guidelines §482.54(c)

Orders for outpatient services may be made by any practitioner who is:

- *Responsible for the care of the patient;*
- *Licensed in, or holds a license recognized in, the jurisdiction where he/she provides care to the patient;*
- *Acting within his/her scope of practice under State law; and*
- *Authorized by the medical staff to order the applicable outpatient services under a written hospital policy that is approved by the governing body. This includes both practitioners who are on the hospital medical staff and who hold medical staff privileges that include ordering the services, as well as other practitioners who are not on the hospital medical staff, but who satisfy the hospital's policies for ordering applicable outpatient services.*

This regulation allows hospitals to accept orders for outpatient services both from practitioners who hold hospital privileges as well as practitioners who do not, including those who are not located in the hospital's close geographic area.

It is not uncommon for individuals to obtain health care services in a variety of locations from a variety of practitioners. Sometimes an individual elects to seek services from a specialist in a tertiary setting removed from the area where the individual lives, but prefers to get follow-up care, such as physical therapy after a surgery, closer to home. Sometimes an individual may have multiple residences in different areas and may need to continue care locally when moving between residences. Sometimes individuals receive urgent or even emergent care while traveling. Accepting orders and referrals for outpatient services from practitioners not on the medical staff or not holding privileges enables a hospital to promote ready access to care for patients in the area it serves. Finally, sometimes a practitioner who does not practice in a local hospital may nevertheless refer patients to that hospital for outpatient services, such as diagnostic imaging, physical and occupational therapy, etc.

The authority to write orders for outpatient services is covered under the hospital's medical staff privileging process for members of the hospital's medical staff and for practitioners who have been granted privileges by the hospital without being appointment to the medical staff.

For practitioners who do not hold hospital privileges the hospital's medical staff policy may permit them to refer patients to the hospital with orders for specific outpatient services so long as all of the above criteria are met. The policy must address how the hospital verifies the referring/ordering practitioner is appropriately licensed and acting within his/her scope of practice. The regulation does not prescribe the details of the licensure and scope of practice verification process but instead provides a hospital the flexibility to accomplish this in the manner it finds efficient and effective. The hospital is expected to ensure the verification process is followed for all outpatient services in all hospital locations.

The policy must also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with medical staff privileges. For example, a hospital may prefer not to accept orders for a regimen of outpatient chemotherapy or outpatient therapeutic nuclear medicine services from a referring physician who does not hold medical staff privileges. In such cases, the hospital's policy must make these exceptions clear to the general authorization for accepting orders from referring practitioners.

Survey Procedures §482.54(c)

- *Survey a variety of settings that offer outpatient services. Ask department staff whether orders or referrals for that type of outpatient service are accepted from practitioners who do not hold hospital privileges. If yes:*
 - *Ask for evidence that the medical staff has adopted the policy.*
 - *Ask how the hospital verifies that the order or referral comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she provides care to the patient and is practicing within his/her scope of practice under State law to prescribe such orders. Ask for documentation of such verification efforts.*
 - *Ensure the same verification process is followed consistently in all outpatient settings.*

A-1081

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

Standard-level Tag for

§482.54 Condition of Participation: Outpatient Services

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretive Guidelines §482.54

This is an optional hospital service; however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP).

The Medicare Hospital CoP apply to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations.

All outpatient services provided by the hospital, both on campus and at any provider-based clinics, must meet the needs of the patients, in accordance with acceptable standards of practice. The hospital must ensure that services, equipment, staff, and facilities are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc.).

If the hospital offers outpatient surgical services, the Surgical Services CoP (§482.5) requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered.

The hospital's outpatient services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.54

- Verify that equipment, staff and facilities are adequate to provide the outpatient services offered at each location are in accordance with acceptable standards of practice.
- Verify that outpatient services at all locations are in compliance with the hospital CoP.
- Determine locations and type(s) of outpatient services provided.
- Verify that the hospital's outpatient services are integrated into its hospital-wide QAPI program.

A-1132

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.56(b) Standard: Delivery of Services

Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

Interpretive Guidelines §482.56(b)

Rehabilitation services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient. The practitioner must have medical staff privileges to write orders for these services or, for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at §482.54(c).

For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing rehabilitation services developed by the medical staff.

Practitioners who may be granted privileges to order rehabilitation services include physicians, and may also, in accordance with hospital policy, include Nurse Practitioners, Physicians' Assistants, and Clinical Nurse Specialists as long as they meet the parameters of this requirement. Although the following licensed professionals are also considered "practitioners" in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient with regard to rehabilitation services or qualified to order rehabilitation services: Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act); Certified nurse-midwife (Section 1861(gg)(2) of the Act); Clinical social worker (Section 1861(hh)(1) of the Act); Clinical psychologist (for purposes of Section 1861(ii) of the Act and as defined at 42 CFR 410.71); or registered dietician or nutrition professional.

Survey Procedures §482.56(b)

- Review medical records of patients receiving rehabilitation services. Determine who wrote the orders for the rehabilitation services. Determine if the practitioner is responsible for the care of the patient and privileged to write orders for rehabilitation services. Verify the practitioner meets hospital medical staff policy criteria to order services as well as State law for ordering rehabilitation services.*
- Does the hospital permit acceptance of orders from outside practitioners who do not practice at the hospital? If so, evaluate for compliance with §482.54(c).*

A-1163

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§482.57(b)(3) - Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

Interpretive Guidelines §482.57(b)(3)

Respiratory care services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient. The practitioner must have medical staff privileges to write orders for these services or, for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at §482.54(c).

For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing respiratory care services developed by the medical staff.

Practitioners who may be granted privileges to order respiratory care services include physicians, and may also, in accordance with hospital policy, include Nurse Practitioners, Physicians' Assistants, Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives as long as they meet the parameters of this requirement. Although the following licensed professionals are also considered practitioners, in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient with regard to respiratory care services or qualified to order respiratory care services: Clinical social worker (Section 1861(hh)(1) of the Act and as defined in 42 CFR 410.71); Clinical psychologist (for purposes of Section 1861(ii) of the Act); or registered dietician or nutrition professional.

Survey Procedures §482.57(b)(3)

- Review medical records of patients receiving respiratory care services. Determine who wrote the orders for the respiratory care services. Determine if the practitioner is responsible for the care of the patient and privileged to write orders for respiratory care services. Verify the practitioner meets hospital medical staff policy criteria to order services as well as State law for ordering respiratory care services.*
- Does the hospital permit acceptance of orders from outside practitioners who do not practice at the hospital? If so, evaluate for compliance with §482.54(c).*

State Operations Manual

Appendix G - Guidance to Surveyors: Rural Health Clinics (RHCs) –

Table of Contents
(Rev. 136, Issued: 03-27-15)

Transmittals for Appendix G

INDEX

- §491.4 Condition for Certification : Compliance With Federal, State, and Local Laws
- §491.5 Condition for Certification: Location of Clinic
- §491.6 Condition for Certification: Physical Plant and Environment
- §491.7 Condition for Certification: Organizational Structure
- §491.8 Condition for Certification: Staffing and Staff Responsibilities
- §491.9 Condition for Certification: Provision of Services
- §491.10 Condition for Certification: Patient Health Records
- §491.11 Condition for Certification: Program Evaluation

§491.8 Condition for Certification: Staffing and Staff Responsibilities
(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

(a) Staffing.

(1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

(b) Physician responsibilities. The physician performs the following:

(1) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(2) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients.

(3) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(c) Physician assistant and nurse practitioner responsibilities. (1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's or center's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

In accordance with §491.2, “Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).”

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When *staffing meets the minimum requirement but appears insufficient for the services the RHC provides*, explain, with reasonable detail, the circumstances (and *RHC's* efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain *the services of a physician on a permanent basis, as well as arrangements it has made for immediate*

temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services *on the clinic's premises (including a mobile unit)* at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant must be available to furnish patient care services at least 50 percent of the operating hours during which RHC services are offered, even *when* a physician is *also* present in the clinic. *All time present in the clinic during the clinic's operating hours, even if not actually providing RHC services to patients, may be counted toward the 50 percent requirement. In addition, when RHC services are furnished to clinic patients outside of the clinic (e.g. in the patient's home, in a SNF or other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.*

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic *offers* RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant

must be available to furnish patient care services *during all* 28 hours . Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available *on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence* at least 14 hours (50 percent of 28 hours) to furnish patient care services.

In some cases, the clinic's weekly schedule may not be a *reasonable* period of time on which to base these determinations, and consideration of the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when *its* schedule offering RHC services is *very limited*. An example would be a clinic *where* RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available *on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence* at least 9 hours to furnish patient care services. *This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant was on-site on one Tuesday for 3 hours and on the Friday for 6 hours, or through some other schedule that results in their availability 9 hours/month.*

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

1 - Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

- *Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.*
- *Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.*
- *Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.*

A physician member *must* perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), *but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at the RHC. With the development of technology that facilitates telemedicine, a physician has the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.*

2 - Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities

The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is performing the necessary responsibilities *at 42 CFR 491.8(c)(1) and (2).*

State Operations Manual

Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

Table of Contents
(Rev. 136, Issued: 03-27-15)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol

Introduction

Regulatory and Policy References

Tasks in the Survey Protocol

- Task 1 – Off-Site Survey Preparation
- Task 2 – Entrance Activities
- Task 3 – Information Gathering/Investigation
- Task 4 – Preliminary Decision Making and Analysis of Findings
- Task 5 – Exit Conference
- Task 6 – Post-Survey Activities

Part II - General Provisions and Definitions; General Conditions and Requirements

§416.2 - Definitions

§416.25 Basic Requirements

Specific Conditions for Coverage

- §416.40 Condition for Coverage: Compliance With State Licensure Law
- §416.41 Condition for Coverage: Governing Body and Management
- §416.42 Condition for Coverage: Surgical Services
- §416.43 Condition for Coverage: Quality Assessment and Performance Improvement
- §416.44 Conditions for Coverage: Environment
- §416.45 Condition for Coverage: Medical Staff
- §416.46 Condition for Coverage: Nursing Service
- §416.47 Condition for Coverage: Medical Records
- §416.48 Condition for Coverage: Pharmaceutical Services
- §416.49 Condition for Coverage: Laboratory and Radiologic Services
- §416.50 Condition: Patient Rights

§416.51 Condition: Infection Control

§416.52 Condition: Patient Admission, Assessment and Discharge

Q-0042

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§416.41(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 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 a hospital that meets the requirements of paragraph (b)(2) of this section.**

Interpretive Guidelines: §416.41(b)

The ASC must be able to transfer a patient immediately to a local hospital when the patient experiences a medical emergency that the ASC is not capable of handling, or which requires emergency care extending well beyond the 24-hour time frame for ASC cases. (See §§416.44(c) and (d) for a discussion of the emergency care capabilities each ASC must have.)

(1) Immediate Transfer Procedure

An “effective procedure” for immediate emergency transfers includes:

- Written ASC policies and procedures that address the circumstances warranting emergency transfer, including who makes the transfer decision; the documentation that must accompany the transferred patient; and the procedure for accomplishing the transfer safely and expeditiously, *including communicating with the receiving hospital*. There must be evidence that staff are aware of and can implement the ASC’s policy immediately upon the development of a medical emergency.
- Provision of emergency care and initial stabilizing treatment within the ASC’s capabilities until the patient is transferred. (See §§416.44(c) and (d).)

- Arrangement for immediate emergency transport of the patient. (It is acceptable if the ASC contacts the ambulance service via 911 to arrange emergency transport, unless State licensure requires additional arrangements, *but the ASC is still responsible for communicating with the receiving hospital to facilitate the transfer.*)

(2) Transfer to a local hospital

The ASC is required to transfer patients who require emergency transfer to *a* local Medicare-participating hospital, or to a local, non-Medicare-participating hospital that meets the requirements for payment for emergency services by the Medicare program in accordance with 42 CFR 482.2. (See the interpretive guidelines for §482.2 in Appendix A of the State Operations Manual *concerning non-participating emergency hospitals.*)

A “local” hospital means the ASC is to consider the most appropriate facility to which the ASC will transport its patients in the event of an emergency. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the type of surgeries performed by the ASC, *another hospital that is able to do so and which is closer than other comparable hospitals would* meet the “local” definition. *For example, if there is a long term care hospital within five miles of the ASC, and a short-term acute care hospital providing emergency services within fifteen miles of the ASC, the ASC would be expected to transfer patients to the short-term acute care hospital.*

Patient-specific circumstances play a role in determining the appropriate local hospital at the time of an emergency. For example, if the patient had a heart attack during surgery at the ASC and needs an interventional cardiac catheterization, and the closest hospital does not offer this service, it is expected that the ASC would transfer the patient to a farther hospital with the cardiac catheterization capability.

If there are multiple hospitals with comparable capabilities that are roughly the same distance from the ASC, i.e., there are only a few miles difference among them in their distance from the ASC, then the ASC may make the transfer to any one of these hospitals. For example, if there are three comparable, appropriate hospitals within a ten mile radius of the ASC, transfer to any one would be acceptable. Likewise, for another example, if the ASC is in a more rural area and there are two appropriate hospitals that are each about 40 miles distant from the ASC, but in opposite directions, each of those hospitals would be considered a “local” hospital for the ASC.

On the other hand, for example, if there is an appropriate hospital eight miles from the ASC, and another hospital with similar capabilities twenty miles from the ASC, the further hospital would not be considered a local hospital for ASC emergency transfer purposes, unless the closer hospital lacks capacity at the time of the transfer.

A State-specific definition of what constitutes a “local” hospital for ASC transfer purposes does not override the Medicare requirement to use the hospital nearest to the ASC with the appropriate capabilities.

CMS expects that, absent the specific types of circumstances described above, emergency transfers will ordinarily be made to a hospital with which the ASC has an arrangement(s) to meet the requirements of §416.41(b)(2) and (3). Regardless of any business issues that may arise between ASCs and their local hospital(s), the ASC is required to *have an effective procedure to immediately* transfer its emergency cases to the nearest, most appropriate local hospital, since a delay in transfer could affect the patient’s health. (See 72 FR 50472, August 31, 2007 and 73 FR 68714, November 18, 2008.)

(3) Transfer Agreement or Hospital Privileges

The ASC is required to:

- Have a written transfer agreement that is in force with a hospital that meets the requirements at §416.41(b)(2); or
- Ensure that every physician performing surgery at the ASC has admitting privileges at a hospital that meets the requirements of §416.41(b)(2).

A transfer agreement is a written agreement, signed by authorized representatives of the ASC and the hospital, in which the hospital agrees to accept the transfer of the ASC’s patients who need inpatient hospital care, including emergency care. Generally transfer agreements establish the respective responsibilities of each party to the agreement, such as the process for arranging a transfer, etc. A transfer agreement may have an expiration date, or it may have terms stating that it remains in effect until and unless one of the parties has terminated the transfer agreement. An ASC’s transfer agreement must be reviewed to determine whether it is in force at the time of the survey.

If the ASC does not have a transfer agreement, then it must maintain documentation of the current admitting privileges of all physicians who perform surgery at the ASC at local hospitals that satisfy the regulatory requirements in §416.41(b)(2) . (Even if the ASC has a transfer agreement, such documentation would be a good idea. However, it is required under the regulations only if there is no transfer agreement.) If there is more than one local hospital that meets the regulatory requirement for an appropriate local transfer destination, the ASC may satisfy the requirement at §416.41(b)(3) when its operating physicians each have admitting privileges at one of the eligible hospitals; it is not necessary that they all have privileges in the same hospital. The physician who performed the surgery on the patient requiring an emergency transfer is expected to arrange the hospital admission of the patient, unless there is a compelling clinical reason to transfer the patient to a different local hospital where the physician does not have admitting privileges.

In some circumstances, a transfer agreement *between the ASC and a local hospital* or the possession of hospital admitting privileges by the ASC's operating physicians *will* not guarantee that a hospital will accept a specific transfer, since the hospital may lack the capacity to provide the required service at the time an emergency transfer request is made. ASCs should have alternative plans to address such contingencies. While it is true that the local hospital, if it is a Medicare-participating hospital that has an emergency department, would be obligated under the Emergency Medical Treatment and Labor Act (EMTALA), once the patient arrives on the hospital's property, to provide a medical screening examination, as well as stabilizing treatment to an individual with an emergency medical condition, an ASC may not satisfy its transfer requirements by simply relying upon *an expectation that* hospitals *fulfill their* EMTALA obligations. An ASC may call 911 to arrange emergency transport, but it must also take steps to arrange the *transfer* of the patient *to* a local hospital.

Survey Procedures: §416.41(b)

- *Before going on the survey, determine which hospital(s) in the vicinity of the ASC might meet the regulatory requirement of being a local hospital.*
- *Determine whether the ASC has a transfer agreement with an appropriate local hospital that meets the regulatory requirements. If it does, ask to see the transfer agreement. Look for an expiration date. If there is no expiration date, ask the ASC whether the transfer agreement has been terminated by either party. If there is doubt about the transfer agreement being in effect, a surveyor may contact the hospital to ask it whether it has a current transfer agreement with the ASC.*
- *If the ASC does not have a transfer agreement with an appropriate local hospital, ask for documentation that each physician who has privileges to perform surgery in the ASC has admitting privileges in an appropriate local hospital. Ask the ASC how it ensures that its information is up-to-date.*
- Ask to see the ASC's policy and procedures for emergency transfer of patients. Review the document to determine whether it addresses the essential elements.
- How is this protocol communicated to the clinical staff of the ASC?
- Ask the clinical staff how they would handle a medical emergency of an ASC patient that could not be managed within the ASC. Do they know the ASC's policies and procedures for emergency transfer? Do they know how to arrange emergency transport?
- Ask if the ASC has had any emergency transfers of patients in the previous 12 months. If it has, review the medical records of patients transferred to hospitals to determine whether they were transferred to hospitals that meet the regulatory requirements for a local hospital. *If the ASC transfers emergency cases to hospital(s) other than local one(s), ask for the rationale supporting these alternative transfers.*

- Determine whether the ASC had a transfer agreement, or a physician with admitting privileges, at each hospital to which a patient was transferred.
- Does the medical record give any indication that the ASC took steps to arrange the transfer, beyond calling 911?

Q-0060

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§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

The standard level tag for §416.42 (Q-0064) provides more detailed guidance on the requirements for performing surgical services in a safe manner, by qualified physicians. It permits standard-level citations for identified deficiencies.

The manner and degree of noncompliance identified in relation to the standard level tags for §416.42 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Q-0064

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Standard level tag for

§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

Qualified Physician: Surgery in an ASC may only be performed by a qualified physician. With respect to ASCs, a physician is defined in accordance with §1861(r) of the Social Security Act to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. In all cases, the physician must be licensed in the State in which the ASC is located and practicing within the scope of his/her license.

In addition, the regulation requires that each physician who performs surgery in the ASC has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the ASC. The ASC's governing body is responsible for reviewing the qualifications of all physicians who have been recommended by qualified medical personnel and granting surgical privileges as the governing body determines appropriate.

The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials and determining whether to grant privileges and the scope of the privileges for each physician. See the interpretive guidelines for §416.45(a), Medical Staff Membership and Clinical Privileges for further guidance.

Safe Manner: The surgical procedures that take place in the ASC must be performed in a "safe manner." "In a safe manner" means primarily that physicians and other clinical staff follow acceptable surgical standards of practice in all phases of a surgical procedure, beginning with the pre-operative preparation of the patient, through to the post-operative recovery and discharge. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).

In addition, acceptable standards of practice include the use of standard procedures to ensure proper identification of the patient and surgical site, in order to avoid wrong site/wrong person/wrong procedure errors. Generally accepted procedures to avoid such surgical errors require:

- A pre-procedure verification process to make sure all relevant documents (including the patient's signed informed consent) and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the ASC's clinical staff expect to be performed;
- Marking of the intended procedure site by the physician who will perform the procedure or another member of the surgical team so that it is unambiguously clear; and
- A "time out" before starting the procedure to confirm that the correct patient, site and procedure have been identified, and that all required documents and equipment are available and ready for use.

Conducting surgery in a safe manner also requires appropriate use of liquid germicides in the operating or procedure room. It is estimated that approximately 100 surgical fires occur each year in the United States, resulting in roughly 20 serious patient injuries, including one to two deaths annually. Fires occur when an ignition source, a fuel source, and an

oxidizer come together¹. Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery or the use of cautery or lasers involve heat-producing devices. There is concern that an alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location, could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site.

On the other hand, surgical site infections (SSI) also pose significant risk to patients; according to the Centers for Disease Control and Prevention (CDC)², such infections are the third most commonly reported healthcare associated infections. Although the CDC has stated that there are no definitive studies comparing the effectiveness of the different types of skin antiseptics in preventing SSI, it also states that "Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic."³ Hence, in light of alcohol's effectiveness as a skin antiseptic, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infection.

The use of an alcohol-based skin preparation in ASCs is not considered safe, unless appropriate fire risk reduction measures are taken, preferably as part of a systematic approach by the ASC to preventing surgery-related fires. A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following fire risk reduction measures are appropriate:

- Using skin prep solutions that are: 1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and 2) provide clear and explicit manufacturer/supplier instructions and warnings. These instructions for use should be carefully followed;
- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient;

¹ *Tentative Interim Amendment (TIA 05-02) to (National Fire Protection Association) NFPA 99, 2005 edition, 13.4.1.2.2. Germicides and Antiseptics, issued July 29, 2005 and effective August 18, 2005. See also AORN Guidance Statement: Fire Prevention in the Operating Room; and Patient Safety Advisory June 2005 (Vol. 2 No. 2) 14, Prepared by ECRI for the Pennsylvania Patient Safety Reporting System.*

² *CDC Hospital Infection Control Practices Advisory Committee, "Guideline for Prevention of Surgical Site Infection, 1999," Infection Control and Hospital Epidemiology April 1999 (Vol. 20 No. 4) 251.*

³ *Ibid, p. 257*

- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping; and
- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be done, for example, as part of a standardized pre-operative “time out” used to verify other essential information to minimize the risk of medical errors during the procedure.

ASCs that employ alcohol-based skin preparations in ORs or procedure rooms should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient’s medical record.

Failure by an ASC to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in ORs or procedure rooms is cited as condition-level noncompliance with §416.44.

Requirements addressed in other ASC Conditions for Coverage are important components of the provision of surgical services in a “safe manner,” and condition-level deficiencies in these other areas may also constitute condition-level noncompliance with the Surgical Services Condition. These other pertinent ASC regulatory requirements include:

- §416.44(a)(1), concerning operating room design and equipment – for example:
 - The surgical 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;
 - Surgical devices and equipment are monitored, inspected, tested, and maintained by the ASC in accordance with Federal and State law, regulations and guideline, and manufacturer’s recommendations; and that
 - Access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
- §416.44(a)(2), concerning a separate recovery room;
- §416.44(a)(3) and §416.51, concerning infection control, for example:
 - The conformance to aseptic and, when applicable, sterile technique by all individuals in the surgical area;
 - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

- That operating room attire is suitable for the kind of surgical case performed;
- That equipment is available for rapid “emergency” high-level disinfection or, as applicable, sterilization of operating room materials;
- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- That, as applicable, temperature and humidity are monitored and maintained within accepted standards of practice; and
- §416.44(c) & (d), concerning emergency equipment and personnel – for example:
 - That surgical staff are trained in the use of emergency equipment.

Survey Procedures: §416.42

- Determine whether the ASC has policies and procedures that establish the criteria and process the governing body uses when granting surgical privileges to a physician. Ask for documentation that the governing body approved these policies and procedures.
- Ask the ASC to identify each physician who currently has surgical privileges or has had surgical privileges within the previous 6 months. Ask the ASC for documentation of the governing body’s action to grant privileges to each of these physicians. Conduct this review in conjunction with the review of compliance with §§416.45(a)&(b).
- For each surgical case record that is reviewed as part of the survey team’s medical record review, verify that the individual performing the surgery was a physician who had been granted privileges by the ASC’s governing body.
- Observe at least one surgical case from the pre-operative phase through to the recovery room and discharge phase in order to determine whether standard procedures are followed to avoid wrong site/procedure/patient surgical errors, and that the requirements described above are met.
- Determine whether the ASC employs appropriate measures to reduce the risk of surgical fires.
- Ask the ASC whether it has ever had a surgical fire, and if so, what follow-up actions did it take to prevent the recurrence of surgical fires.

Q-0101

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.44(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.**

Interpretive Guidelines: §416.44(a)(1)

State Agencies may wish to assign surveyors who are trained in evaluating healthcare facility design and construction assist in evaluating compliance with this standard. “Operating room” (*OR*) in an ASC includes *not only traditional ORs, but also* procedure rooms, *including those where surgical procedures that do not require a sterile environment are performed.*

ORs must be designed in accordance with industry standards for the types of surgical procedures performed in the room, *including whether the OR is used for sterile and/or non-sterile procedures. Existing ORs must meet the standards in force at the time they were constructed, while new or reconstructed ORs must meet current standards. Although the term “OR” includes both traditional ORs and procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional operating rooms. In all cases, the OR design and equipment must be appropriate to the types of surgical procedures performed in it.*

National organizations, such as the Facilities Guidelines Institute, may be used as a source of guidance to evaluate OR design and construction in an ASC. If a State’s licensure requirements include specifications for OR design and construction, the ASC must, in accordance with §416.40, comply with those State requirements.

The location of the OR within the ASC and the access to it must conform to accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the OR. The movement of staff and patients on stretchers must proceed safely, uninhibited by obstructions.

The OR must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.). Medical equipment for the OR includes the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be

available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into consideration the time required for appropriate cleaning and, if applicable, sterilization. In addition, emergency equipment determined to be necessary in accordance with §416.44(c) must be either in or immediately available to the OR.

The OR equipment must be inspected, tested and maintained appropriately by the ASC, in accordance with Federal and State law (including regulations) and manufacturers' recommendations.

Temperature, humidity and airflow in ORs must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. ASCs must maintain records that demonstrate they have maintained acceptable standards.

An example of an acceptable humidity standard for ORs is the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Addendum D of the ASHRAE standard requires RH in ORs to be maintained between 20 - 60 percent. In addition, this ASHRAE standard has been incorporated into the Facility Guidelines Institute (FGI) 2010 Guidelines for Design and Construction of Health Care Facilities, and has been approved by the American Society for Healthcare Engineering of the American Hospital Association and the American National Standards Institute. *ASCs must also ensure, however, that the OR humidity level is appropriate for all of their surgical and anesthesia equipment, and that supplies which require a different level of humidity than that in the OR are appropriately stored until used.*

Each operating room should have separate temperature control. Acceptable standards for OR temperature, such as those recommended by the Association of Operating Room Nurses (AORN) or the FGI, should be incorporated into the ASC's policy. Equipment for rapid emergency sterilization of OR equipment/materials whose sterility has been compromised must be available on-site. However, an ASC that routinely uses sterilization procedures intended for emergency use only as its standard method of sterilization between cases, in order to reuse surgical instruments, must be cited for violating §§416.44(a)(1) & (3) and the Infection Control Condition at §416.51.

It is not necessary for the ASC to have equipment for routine sterilization of equipment and supplies on-site, so long as this service is provided to the ASC under arrangement.

Survey Procedures: §416.44(a)

- Verify the ASC's ORs meet applicable design standards.
- Verify the ASC has the right kind of equipment in the ORs for the types of surgery it performs.

- Verify the ASC has enough equipment, including surgical instrument sets, for the volume of procedures it typically performs.
- Verify the ASC has evidence, such as logs on each piece of electrical or mechanical equipment, indicating that it routinely inspects, tests, and maintains the equipment.
- Verify who within the ASC is responsible for equipment testing and maintenance.
- Considering the size of the OR and the amount and size of OR equipment, verify there is sufficient space for the unobstructed movement of patients and staff.
- Review the ASC's *temperature and humidity* records for ORs, to ensure that appropriate levels are maintained and that, if monitoring determined temperature or humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.

Q-0122

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§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.

Interpretive Guidelines: §416.45(b)

The ASC's governing body must have a process reappraising the medical staff privileges granted to each practitioner. CMS recommends a reappraisal at least every 24 months. The reappraisal must include:

- Review of the practitioner's current credentials; and
- The practitioner's ASC-specific case record, including measures employed in the ASC's quality assurance/performance improvement program, such as emergency transfers to hospitals, post-surgical infection rates, other surgical complications, etc.

The ASC's governing body should use a similar process, including the recommendation of qualified medical personnel, for the periodic reappraisal as it used when initially granting privileges.

Based on the evidence, the ASC's governing body must decide whether to continue the practitioner's current privileges without change, or to amend those privileges by contracting or expanding them, or by withdrawal of the practitioner's privileges entirely.

The ASC must also reappraise a practitioner any time the practitioner seeks to perform procedures outside the scope of previously granted procedures.

The ASC should also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule.

In the case of an ASC whose sole member of the governing body is also a member of the ASC's medical staff, it would be advisable to seek the recommendation of outside qualified medical personnel who review not only the physician's credentials, but also evidence of the physician's performance in the ASC.

Survey Procedures: §416.45(b)

- Does the ASC periodically reappraise all practitioners granted clinical privileges?
- Ask the ASC's leadership how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?
- Review the personnel records for all practitioners with privileges to practice in the ASC to determine whether they have been reappraised within the timeframe specific in the medical staff policy.
- Do the reappraisals include evidence that data on the practitioner's practice within the ASC is considered along with the practitioner's credentials?

Q-0202

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b) Standard: Radiologic Services.

(1) Radiologic services may only be provided when integral to procedures offered by the ASC ...

Interpretive Guidelines: §416.49(b)(1)

An ASC may only provide radiological services as an integral part of the surgical procedures it performs. Radiological services integral to the procedure itself are those imaging services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure.

If the ASC does not provide these radiological services directly, i.e., utilizing its own staff, then it must obtain them via a contract or other formal arrangement .

Survey Procedures: §416.49(b)(1)

- *Does the ASC provide, either directly or under arrangement, radiologic services? If yes, verify that it performs only those radiologic services that are integral to its surgical services?*

Q-0203

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§416.49(b)(1) [Radiologic services...]

... must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter.

Interpretive Guidelines §416.49(b)(1)

The scope and complexity of radiological services provided within the ASC, either directly or under arrangement, as an integral part of the ASC's surgical services must be specified in writing and approved by the governing body. The ASC must also ensure that the provision of radiological services in the ASC complies with the hospital radiologic services requirements at § 482.26(b), (c)(2), and (d)(2), regardless of whether the service is provided directly by the ASC or under arrangement.

The interpretive guidelines for § 482.26(b), (c)(2), and (d)(2) in Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals of the State Operations Manual, provide the following guidance in determining compliance:

§482.26(b) Standard: Safety for Patients and Personnel

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel.

Survey Procedures §482.26(b)

Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?

§482.26(b)(1) 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.

Interpretive Guidelines §482.26(b)(1)

The hospital policies must contain safety standards for at least:

- Adequate shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Proper storage of radiation monitoring badges when not in use;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- Methods of identifying pregnant patients.

The hospital must implement and ensure compliance with its established safety standards.

Survey Procedures §482.26(b)(1)

- Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the hospital.
- Verify that hazardous materials are stored properly in a safe manner.
- Observe areas where testing is done for violations in safety precautions.

§482.26(b)(2) Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in

accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place, qualified employees or contracts, to correct hazards. The hospital must be able to demonstrate current inspection and proper correction of all hazards.

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.
- Determine that any problems identified are properly corrected in a timely manner.

§482.26(b)(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiological services personnel, as well as, other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include personnel such as certain nursing and maintenance staff.

Survey Procedures §482.26(b)(3)

- Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.
- Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.
- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

§482.26(b)(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

Survey Procedures §482.26(b)(4)

Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with State law.

§482.26(c)(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

Interpretive Guidelines §482.26(c)(2)

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

Survey Procedures §482.26(c)(2)

Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

§482.26(d)(2) The hospital must maintain the following for at least 5 years:

- (i) Copies of reports and printouts**
- (ii) Films, scans, and other image records, as appropriate.**

Interpretive Guidelines §482.26(d)(2)

Patient radiology records are a type of patient medical record. The hospital must maintain radiology records in compliance with the medical records CoP and this CoP. Medical records, including radiology records, must be maintained for 5 years.

Survey Procedures §482.26(d)(2)

- Verify that the hospital maintains records for at least 5 years.
- Verify that radiology records are maintained in the manner required by the Medical Records....” [CfC].

Survey Procedures: §416.49(b)(1)

- *If the ASC provides radiologic services as an integral part of surgical procedures, does it comply with the requirements of §482.26(b), (c)(2), and (d)(2) in its provision of those services, using the hospital radiologic services interpretive guidelines cited above?*

- *Interview the individual designated responsible for assuring compliance with this CfC and review related documentation to assess how these responsibilities have been implemented in the ASC. For example, is there evidence that this individual monitors and/or oversees the monitoring of compliance with all of the requirements in §482.26(b), (c)(2), and (d)(2)? What steps are available to this individual to remedy the situation if there is evidence of noncompliance with any of the requirements?*

Q-0204

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b)(2) *If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.*

Interpretive Guidelines: §416.49(b)(2)

If the ASC provides radiologic services, the ASC's governing body must appoint an individual who has appropriate qualifications, in accordance with State law and Federal regulations, to provide oversight of these services. The appointed individual is responsible for assuring the ASC's compliance with §§ 482.26(b), (c)(2), and (d)(2). In order to assure compliance with these requirements the individual is expected to be qualified, through training and/or experience, to oversee areas including, but not limited to: use of safety precautions (shielding, and appropriate storage, use and disposal of radioactive materials) against radiation hazards; regular equipment inspection and hazard correction; regular review of radiation worker radiation exposure; assuring use of radiologic equipment only by qualified personnel; and maintenance of imaging results or records. The person appointed to oversee radiologic services could be someone already working in the ASC who is qualified in accordance with State law and Federal regulations. Under the medical staff credentialing and privileging requirements at §416.45, the ASC's governing body will continue to be required to ensure that the operating surgeon is competent both to perform the surgical procedures for which privileges have been issued by the ASC and to appropriately and safely use the imaging modalit(ies) that are integral to the procedures s/he performs.

Survey Procedures: §416.49(b)(2)

- *Can the ASC demonstrate that the individual responsible for assuring all radiologic services are provided in accordance with the requirements of this section:*
 - *Is qualified for this role in accordance with State and/or Federal law and regulations and ASC policies?*
 - *Was appointed by the ASC's governing body?*

Q-0221

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of Rights

An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

Interpretive Guidelines: §416.50(a)

The ASC must inform each patient, or the patient's representative or surrogate of the patient's rights. This notice must be provided both verbally and in writing prior to the start of the surgical procedure, i.e., prior to the patient's movement out of the pre-operative area, and, if applicable, before the patient is medicated with a drug(s) that suppresses the patient's consciousness. It is not acceptable for the ASC to provide the notice when the patient has already been moved into the operating room (including procedure room) or has been medicated in such a manner that he or she is not able to follow or remember the provision of notice.

This regulation does not require that in every instance notice be delivered just prior to the start of the surgical procedure. Instead, the regulation indicates the latest acceptable time for delivery of the notice. It would be acceptable for the ASC to mail or e-mail the notice of patient rights in advance of the date of the scheduled procedure, or at the time the patient appears in the registration area on the date of the procedure. CMS recommends that ASCs provide patients notice of their rights as soon as possible after the procedure is scheduled, but so long as notice is provided prior to the start of the surgical procedure, the ASC is in compliance with the regulation.

Notice must be provided regardless of the type of procedure scheduled to be performed.

The regulation does not require a specific form or wording for the written notice, so it is acceptable for the ASC to develop a generic, pre-printed notice for use with all of its patients, as long as the notice includes all of the patient rights established under the regulation.

The notice must include the address and telephone number of the appropriate State agency to which patients may report complaints about the ASC. If available, an e-mail or web address for submission of complaints to the State agency should also be provided.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: <http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html>

Patients who are Medicare beneficiaries, or their representative or surrogates, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

The notice must:

- Address all of the patient's rights under this Condition.
- Be provided and explained in a language and manner that the patient or the patient's representative or surrogate understands, including patients who do not speak English or with limited communication skills. The patient has the choice of using an interpreter of his or her own, or one supplied by the ASC. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the ASC to the patient. In following translation practices, CMS recommends, but does not require, that a written translation be provided in languages that non-English speaking patients can read, particularly for languages that are most commonly used by non-English-speaking patients of the ASC. We note that there are many hundreds of languages (not all written) that are used by one or more residents of the United State, but that in most geographic areas the most common non-English language generally is Spanish. We note there are other applicable legal requirements, most notably, those under title VI of the Civil Rights Act of 1964. The Department of Health and Human Services' (HHS) guidance related to Title VI of the Civil Rights Act of 1964, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (68 FR 47311, Aug. 8, 2003) applies to those entities that receive federal financial assistance from HHS, including ASCs. This guidance may assist ASCs in ensuring that patient rights information is provided in a language and manner the patient understands. The regulation at §416.50(a) is compatible with guidance on Title VI.

Survey Procedures: §416.50(a)

- Determine what the ASC's policy and procedures are for providing all patients and/or their representatives or surrogates notice of their rights prior to the start of the surgical procedure. Are the policies and procedures consistent with the regulatory requirements?
- Determine whether the information provided in the written notice to the patients and/or their representatives or surrogates by the ASC is complete and accurate:

- Does the notice address all of the patients' rights listed in this Condition?
- Does the notice provide the required information about where to file complaints or how to contact the Medicare Ombudsman?
- Is the staff who are responsible for advising patients of their rights aware of the ASC's policies and procedures for providing such notice, including to those patients with special communication needs?
- Review records, interview staff, and observe staff/patient interaction to examine how the ASC communicates information about patient rights to diverse patients, including patients who need assistive devices or translation services.
 - Does the ASC provide all patients with verbal and written notice of their rights prior to the start of the surgical procedure?
 - Does the ASC have a significant number of patients with limited English proficiency? If so, are there written notice materials available for patients who have a primary language other than English? If not, does the ASC have translators available to provide verbal notice of their rights to ASC patients?
- Ask patients to tell you how, when and what the ASC has told them about their rights.

Q-0222

(Rev. 136, Issued: 03-27-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of rights

(1)[...] In addition, the ASC must –

(i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, 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.

Interpretive Guidelines: §416.50(a)(1)(i)

The ASC must ensure that a written notice of patient rights is posted in one or more places where they are likely to be noticed. This would include waiting rooms, recovery rooms, or any other areas where patients and/or their representatives are likely to be. Notices must be posted in at least one area. Posting in more than one area increases the likelihood that patients will see the notice, but an ASC may post only one notice and

comply with the requirement, so long as the notice is posted in an area used by every ASC patient and where it is likely to be noticed.

The notice must include the name, address, and telephone number of a representative in the State survey agency to whom patients and/or their representatives can report complaints. Because there can be staff turnover in the State survey agency, creating a burden for both States and ASCs to keep current the names of State staff, it is sufficient if the notice provides the title of the individual in the State survey agency to whom complaints may be reported, as well as the address and telephone number.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: <http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html>

Patients who are Medicare beneficiaries, or their representative, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

Survey Procedures: §416.50(a)(1)(i)

- Observe waiting rooms, recovery rooms, and other common areas used by patients to see if one or more notices of patient rights are posted. Ensure that the notices are posted in conspicuous locations in the waiting rooms, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area used by every ASC patient.
- Observe notices to see that each notice contains all required information.

Q-0229

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§416.50(e) Standard: Exercise of rights and respect for property and person.

[(1) The patient has the right to the following:]

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

Interpretive Guidelines: §416.50(e)(1)(iii)

As in the case of advance directives, the patient has the right to make an informed decision regarding his/her care in the ASC. The right to make informed decisions means that the patient or patient's representative or surrogate is given the information needed in

order to make "informed" decisions regarding his/her care. The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the ASC. The patient or the patient's representative or surrogate should receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions.

ASCs must utilize an informed consent process that assures patients or their representatives or surrogates are given the information and disclosures needed to make an informed decision about whether to consent to a surgical procedure in the ASC. The primary purpose of the informed consent process in the ASC is to ensure that the patient, or the patient's representative or surrogate, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible physician's professional judgment. Informed consent must be obtained and the informed consent form must be *signed by the patient, or as appropriate, the patient's representative, and* placed in the patient's medical record, prior to surgery. It would be acceptable if the ASC required the physician(s) who perform procedures in the ASC to obtain the patient's informed consent outside of the ASC, prior to the date of the surgery, since this might allow more time for discussion between the patient and physician than would be feasible on the date of the surgery. In such cases, the physician must follow the ASC's informed consent process. In all cases, the ASC must ensure that the patient's informed consent is secured prior to the start of the surgical procedure, and that this consent is documented in the patient's medical record. (See the interpretive guidelines for §416.47(b)(7) concerning documentation in the medical record of informed consent.)

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure. The ASC's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;
- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery (see guidance for §416.50(e)(2) & (3));
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;

- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and
- If the informed consent process and informed consent form are obtained outside the ASC, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

If there are additional requirements under State law for informed consent, the ASC must comply with those requirements.

Example of a Well-Designed Informed Consent Process

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner will be performing important tasks related to the surgery, in accordance with the ASC's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

Survey Procedures: §416.50(e)(1)(iii)

- Determine whether the ASC has an informed consent policy that meets the regulatory requirements.
- Verify in the survey sample of medical records that there is documentation that informed consent was given prior to the surgical procedure. *Was the consent signed by the patient or as appropriate, the patient's representative?*
- As part of the process of following one or more cases from start to finish, determine whether there is an informed consent that was executed prior to the surgery date on file, and if not, observe whether the ASC obtains informed consent.
- Check the records of patients who are in recovery on the date(s) of the survey to verify that there is documentation of informed consent.
- Interview patients to determine whether they recall being asked to consent to the procedure, and whether the risks and benefits were discussed with them at that time.

Q-0266

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§416.52(c) Standard: Discharge.

The ASC must -

(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.

Interpretive Guidelines: §416.52(c)(2)

No patient may be discharged from the ASC unless the physician who performed the surgery or procedure signs a discharge order. The ASC must ensure that physicians follow applicable State laws as well as generally accepted standards of practice and ASC policy when determining that a patient has recovered sufficiently from surgery and may be discharged from the ASC, or, as applicable, that the patient must be transferred to another healthcare facility that can provide the ongoing treatment that the patient requires and that the ASC is unable to provide. *It is permissible for the operating physician to write a discharge order indicating “the patient may be discharged when stable.” (73 FR 68721). In such cases there must be documentation of when patient was stable.* It is expected that a patient will actually leave the ASC within 15 – 30 minutes of the time when the physician signs the discharge order *or when he or she was found to be stable, whichever happens later.*

Survey Procedures: §416.52(c)(2)

- Determine whether there is a discharge order, signed by the physician who performed the surgery/procedure, in the sample of medical records being reviewed.
- Determine whether there is a discharge order signed by the physician for patients being discharged while the survey takes place.

State Operations Manual

Appendix T - Regulations and Interpretive Guidelines for Swing Beds in Hospitals

Table of Contents
(Rev. 136, Issued: 03-27-15)

Transmittals for Appendix T

§482.**66** Special Requirements for Hospital Providers of Long-Term Care Services
("Swing-Beds")

§482.**66**(a) Eligibility

§482.**66**(b) Skilled Nursing Facility Services

A-1500

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§482.58 Special Requirements for Hospital Providers of Long-Term Care Services (“Swing-Beds”)

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in §409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in §413.114 of this chapter:

Interpretive Guidelines §482.58

Surveyors assess the manner and degree of non-compliance with the swing bed standards in determining whether there is condition-level compliance or non-compliance.

A-1501

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§482.58(a) Eligibility

A hospital must meet the following eligibility requirements:

- (1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see §413.24(d)(5) of this chapter).*
- (2) The hospital is located in a rural area. This includes all areas not delineated as “urbanized” areas by the Census Bureau, based on the most recent census.*
- (3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.*
- (4) The hospital has not had a swing-bed approval terminated within the two years previous to application.*

Interpretive Guidelines §482.58

The swing-bed concept allows a hospital to use their beds interchangeably for either acute-care or post-acute care. A “swing-bed” is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Allowing a hospital to operate swing-beds is done by issuing a “swing-bed approval.” If the facility fails to meet the swing-bed “requirements” (not the same as the provider CoPs), and the facility chooses not to initiate a plan of correction, they lose the approval

to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the hospital continues to meet the CoPs for the provider type, *it continues to participate in Medicare*, but loses swing-bed approval.

Swing beds do not have to be located in a special section of the hospital. The patient does not have to change locations in the *hospital* merely because their status changes unless the *hospital* requires it. The change in status from acute care to swing-bed status can occur within *the same part of the hospital* or the patient can be *moved* to another *part of the hospital* for swing-bed admission. *Likewise, a patient may be discharged from one hospital and admitted in swing bed status to another hospital that has swing bed approval.*

There must be discharge orders changing status from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same *hospital* or transfers to another *hospital with swing bed approval*. If the patient *remains within the hospital*, the same chart can be utilized but the swing-bed section of the chart must be separate, with appropriate admission orders, progress notes, and supporting documents.

There is no length of stay restriction for any hospital swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between hospitals and nursing homes.

The statute governing Medicare payment requires a 3-day qualifying stay in any hospital or CAH prior to admission to a swing bed in any hospital or CAH, or *admission to a skilled nursing facility* (SNF). The *Medicare beneficiary's* swing-bed stay must fall within the same spell of illness as the qualifying stay. This requirement *applies only* to patients who are Medicare *beneficiaries who seek Medicare coverage of their SNF services*. *It is not enforced through the survey and certification process, since it is a payment requirement.*

In accordance with SOM Section 2037 hospitals seeking swing bed approval are screened prior to survey for their eligibility for swing beds. However, the CMS Regional Office makes the determination whether the hospital has satisfied the eligibility criteria, regardless of whether the State Survey Agency or Accrediting Organization, as applicable, recommends approval of swing bed status.

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§482.58(b) Skilled Nursing Facility Services

The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§483.10(b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m));

(2) Admission, transfer, and discharge rights §483.12(a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7);

(3) Resident behavior and facility practices (§483.13);

(4) Patient activities (§483.15(f));

(5) Social services (§483.15(g));

(6) Discharge planning (§483.20(l));

(7) Specialized rehabilitative services (§483.45);

(8) Dental services (§483.55).