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Aspen Federal Regulation Set: Q 10.02 AMBULATORY SURGICAL CENTERS

FED - Q0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline

FED - Q0001 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

Type Condition

CFR 416.25

Regulation Definition

Interpretive Guideline

Participation as an ASC is limited to facilities that-

- (a) Meet the definition in §416.2; and
- (b) Have in effect an agreement obtained in accordance with this subpart.

An ASC must satisfy all the elements of the definition of an ASC and have in effect an agreement to participate as an ASC in order to satisfy the basic Medicare ASC requirements

FED - Q0002 - DEFINITIONS

Title DEFINITIONS

Type Standard

CFR 416.2

Regulation Definition

Interpretive Guideline

As used in this part:
Ambulatory surgical center or ASC means any distinct entity

According to the definition of an Ambulatory Surgical Center, or ASC, its key characteristics are that it:

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that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part. The ambulatory surgical center must comply with state licensure requirements.

- o Is a distinct entity;
- o Operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following an admission;
- o Has an agreement with Medicare to participate as an ASC; and
- o Complies with the Conditions for Coverage (CfCs) in Subparts B and C, i.e., 42 CFR 416.25-52.

Distinct Entity

An ASC satisfies the criterion of being a "distinct" entity when it is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician practice. The ASC is not required to be housed in a separate building from other healthcare facilities or physician practices, but, in accordance with National Fire Protection Association (NFPA) Life Safety Code requirements (incorporated by cross-reference at §416.44(b)), it must be separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are State licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.

An ASC does not have to be completely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, so long as they are separated in their usage by time. For example:

- o **Adjacent physician office:** Some ASCs may be adjacent to the office(s) of the physicians who practice in the ASC. Where permitted under State law, CMS permits certain common, non-clinical spaces, such as a reception area, waiting room, or restrooms to be shared between an ASC and another entity, as long as they are never used by more than one of the entities at any given time, and as long as this practice does not conflict with State licensure or other State law requirements. In other words, if a physician owns an ASC that is located adjacent to the physician's office, the physician's office may, for example, use the same waiting area, as long as the physician's office is closed while the ASC is open and vice-versa. The common space may not be used during concurrent or overlapping hours of operation of the ASC and the physician office. Furthermore, care must be taken when such an arrangement is in use to ensure that the ASC's medical and administrative records are physically separate. During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.

Permitting use of common, non-clinical space by distinct entities separated temporally does not mean that the ASC is relieved of the obligation to comply with the NFPA Life Safety Code standards for ASCs, in accordance with §416.44(b), that require, among other things, a one-hour separation around all physical space that is used by the ASC and fire alarms in the ASC.

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It is not permissible for an ASC during its hours of operation to "rent out" or otherwise make available an OR or procedure room, or other clinical space, to another provider or supplier, including a physician with an adjacent office.

- o Facilities with Diagnostic Imaging and Surgery Capability: Some facilities are equipped to perform both ambulatory surgeries and diagnostic imaging. However, Medicare regulations do not recognize a non-hospital institutional healthcare entity that performs both types of services, and actually requires an ASC to operate exclusively for the purpose of providing surgical services. However, the Medicare Independent Diagnostic Testing Facility (IDTF) payment regulations at 42 CFR 410.33(g) prohibit IDTFs that are not hospital-based or mobile from sharing a practice location with another Medicare-enrolled individual or organization. As a result, ASCs may not share space, even when temporally separated, with a Medicare-participating IDTF.

NOTE: Certain radiology services integral to surgical procedures may be provided when the facility is operating as an ASC.

- o Separately Certified ASCs Sharing Space: Where permitted under State law, several different ASCs, including ones that participate in Medicare and ones that do not, may use the same physical space, including the same operating rooms, so long as they are temporally distinct, i.e., they do not have concurrent or overlapping hours of operation. However, an ASC and a hospital or CAH outpatient surgery department, including a provider-based department that is either on or off the hospital's or CAH's main campus, may not share the same physical space, since the regulations at 42 CFR 413.65(d)(4) require that the provider-based department be held out to the public as a part of the main hospital, and that patients entering the provider-based facility are aware that they are entering the hospital.

Each of the different ASCs that utilize the same space is separately and individually responsible for compliance with all ASC Conditions for Coverage (CfCs). So, for example, each ASC must have its own policies and procedures and its own medical records. Likewise, although there is no prohibition against each ASC using the same nursing and other staff under an arrangement with the employer of the staff, each is nevertheless required to separately comply with all requirements governing the utilization of staff in the ASC.

At the same time, each Medicare-certified ASC that shares the same space as another Medicare-certified ASC should be aware, when entering into such an arrangement, that identification of certain deficient practices may result in citation of deficiencies for all ASCs occupying the same premises. For example, building features that violate the Life Safety Code would not vary according to which ASC happened to be operating on the premises at the time of a survey, and all ASCs at that location would be cited for the deficiency.

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If there are multiple ASCs utilizing the same space, but at different times, it may be prudent to consider organizing recertification surveys in order to use the time on-site to conduct multiple surveys allowing assessment of each ASC that utilizes the space.

Exclusive Provision of Limited Surgical Services

The ASC must offer only surgical services. Separate ancillary services that are integral to the surgical services, i.e., those furnished immediately before, during or immediately after a surgical procedure, may be provided. The ASC may not, however, offer services unrelated to the surgeries it performs.

What constitutes "surgery"?

For the purposes of determining compliance with the ASC definition, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons (www.facs.org/fellows_info/statements/st-11.html.) Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery:

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician.) All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

An ASC is further limited to providing surgical services only to patients who do not require hospitalization after the surgery. Further, the ASC's surgical services must be ones that ordinarily would not take more than 24 hours, including not just the time for the surgical procedure but also pre-op preparation and recovery time, following the admission of an ASC patient. These limitations apply to all of the ASC's surgical services, not just to surgeries on Medicare beneficiaries who use the ASC.

- o The term "hospitalization" means that a patient needs a supervised recovery period in a facility that provides hospital inpatient care. Whether a patient "requires" hospitalization after a surgical procedure is a function both of

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the characteristics of the patient and of the nature of the surgery. In other words, an ASC might be an appropriate setting for a particular surgical procedure for patients under the age of 65 without significant co-morbidities, but might be a very risky, inappropriate setting for that same procedure when performed on a 75-year old patient with significant co-morbidities. ASCs must consider patient-specific characteristics that might make hospitalization more likely to be required when determining their criteria for patient selection.

Any surgery for which a patient must be routinely transferred to a hospital after the surgery is not appropriate for the ASC setting.

Some States permit the operation of "recovery centers" that are neither Medicare-certified healthcare facilities nor licensed hospitals, but which provide post-operative care to non-Medicare ASC patients. If such recovery centers would be considered hospitals if they participated in the Medicare program, then it is doubtful that an ASC that transfers patients to such centers meets the Medicare definition of an ASC. However, surveyors are not expected to make determinations about the nature of such recovery centers. If a SA is concerned that a recovery center is providing hospital inpatient care, it should discuss this matter further with the CMS Regional Office.

- o Expected duration of services. ASCs may not provide services that, under ordinary circumstances, would be expected to exceed 24 hours following an admission. Patients admitted to an ASC will be permitted to stay 23 hours and 59 minutes, starting from the time of admission (see 73 FR at 68714 (November 18, 2008)). The time calculation begins with the admission and ends with the discharge of the patient from the ASC after the surgical procedure. While the time of admission normally would be the time of registration or check-in of the patient at the ASC's reception area, for the purposes of compliance with this requirement ASCs may use the time when the patient moves from the waiting/reception area into another part of the ASC. This time must be documented in the patient's medical record. The discharge occurs when the physician has signed the discharge order and the patient has left the recovery room. Other starting or end points, e.g., time of administration of anesthesia, or time the patient leaves the OR, may not be used to calculate compliance with the 24-hour requirement.

This requirement applies to all ASC surgical services. For services to Medicare beneficiaries there are additional payment regulations that further limit the surgical services that Medicare will pay for. For example, payment regulations at §416.166(b) state, among other criteria, that Medicare will generally pay for surgical procedures for which standard medical practice dictates that the beneficiary would not typically require active medical monitoring and care after midnight of the day of the procedure. This more restrictive Medicare payment requirement is enforced through the claims payment and audit processes. The SA surveyors may not cite an ASC for failing to meet the definition of an ASC if instances of Medicare beneficiaries who remain in the ASC are identified, so long as they meet the 24-hour requirement.

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Rare instances of patients whose length of stay in the ASC exceeds 24 hours do not automatically mean that the ASC fails to meet the regulatory definition of an ASC and must be cited as out of compliance with this requirement. The regulatory language refers to surgical services whose "expected duration" does not exceed 24 hours. It is possible for an individual case to take longer than expected, due to unforeseen complications or other unforeseen circumstances. In such rare cases the ASC continues to be responsible for the care of the patient until the patient is stable and able to be discharged in accordance with the regulatory requirements governing discharge, as well as the ASC's policy. However, if an ASC has cases exceeding 24 hours more than occasionally, this might suggest that the facility is not in compliance with the definition of an ASC.

Cases that surveyors identify which exceed 24 hours must be reviewed further to determine whether the expected duration of services for the procedure in question, when performed on a patient with key clinical characteristics similar to those of the patient in the case, would routinely exceed 24 hours. Key clinical characteristics include, but are not limited to, age and co-morbidities. If the procedure is one that Medicare pays for in an ASC setting, then it can be assumed that the expected duration of services related to that procedure would not exceed 24 hours. If the procedure is not one that Medicare pays for in an ASC, then the ASC must provide evidence supporting its expectation that the services to the patient would not exceed 24 hours. Such evidence could include other cases in the ASC where similar patients (in terms of condition prior to surgery) undergoing the same procedure were discharged in 24 hours or less after admission.

In summary, exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

ASCs should be aware that, to the extent that patients remain within the ASC for 24 hours or longer, for purposes of Life Safety Code requirements the ASC would be considered a "healthcare" rather than an "ambulatory" occupancy under the NFPA Life Safety Code.

Has a Medicare Supplier Agreement

An entity cannot be an ASC, as that term is defined in Medicare's regulations, if it does not have an agreement to participate in Medicare as an ASC. Since ASCs are suppliers, the ASC agreement is a supplier agreement. Thus, while Medicare regulations recognize, for example, non-participating hospitals and will pay them for emergency services under certain circumstances, in the case of an ASC, the term "ASC" has a meaning exclusive to the entity's

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participation in the Medicare program. Applicants to participate as an ASC are not considered "ASCs" until they actually have a Medicare agreement in place.

In the case of a prospective ASC undergoing an initial survey to determine whether it may be certified for Medicare participation, the SA may not conduct the survey until the Medicare Administrative Contractor/legacy Carrier has reviewed the ASC's Form 855B enrollment application and made a recommendation for approval of the ASC's participation in Medicare.

Compliance with Subparts B and C

Finally, an ASC must comply with each of the requirements found in Subparts B and C, i.e., the provisions found at 42 CFR 416.25 - 35 for Subpart B, and 42 CFR 416.40 - 52 for Subpart C.

Subpart B contains the supplier agreement requirements for an ASC. Enforcement of these provisions generally follows the same process as that outlined in SOM §3030. Although §3030 specifically addresses failures of providers to comply with the statutory provider agreement requirements, noncompliance of an ASC supplier with the provisions of Subpart B may be handled by CMS Regional Offices in the same way.

Subpart C contains the health and safety standards for ASCs, i.e., the Conditions for Coverage. State Survey Agencies survey ASCs for their compliance with the ASC definition and the CfCs. If an ASC has condition-level noncompliance with numerous CfCs, then condition-level noncompliance with §416.25 may also be cited.

Survey Procedures:

- o Determine through interview and observation and consultation with the LSC surveyor whether the ASC facility is physically separated by at least a 1 hour separation from any other healthcare facility or physician office.

- o Determine whether it is permissible under State licensure requirements for an ASC to share its physical space with another entity from which it is temporally separated. If sharing physical space that is temporally separate is not permitted under State law, then it is also not permitted under Medicare.

- o Where permitted under State law, if the ASC shares common administrative space with an adjoining or contiguous physician's office or clinic, ask the ASC for evidence that use of this common space by the ASC and the other entity(ies) is not concurrent or overlapping in time. Look for signs or schedules that would confirm that the entities do not use the space at the same time.

- o If an ASC complies with all other elements of the ASC definition but has permitted concurrent use by an

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adjacent physicians office or clinic of common administrative space, this would constitute a standard-level violation. However, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in a condition-level violation of §416.25 and possibly the other CfCs.

- o Where sharing of space by multiple healthcare entities is permitted under State law, determine through interview, observation and review of facility documents whether the ASC shares the same space, including clinical space, such as ORs, procedure rooms, recovery rooms, etc., with another entity.
- o If it does share space with other healthcare entities, ask the ASC for evidence that the two entities never operate concurrently or have overlapping hours. Look for signs or schedules that would confirm that the entities do not use the same space at the same time.
- o If there are multiple ASCs utilizing the same space and there are deficiencies that are common to more than one ASC, citations must be issued to each ASC.
- o If there is evidence that ASC and another entity that provides services other than surgery share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a condition-level violation of §416.25 because the ASC would not be a distinct entity and it would not be operating exclusively to provide surgical services. In addition, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in additional condition-level violations.
- o If there is evidence that ASC and another entity that provides surgical services share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a standard-level violation. However, this co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in condition-level violation of §416.25 and possibly the other CfCs.
- o Review all closed medical records in the survey sample to determine whether the time elapsed between the patient's admission or registration and discharge does not exceed 23 hours and 59 minutes. The calculation of the timeframe begins with the time documented in the medical record indicating when the patient moved from the reception or waiting area into another part of the ASC, if the ASC records this separate from the time of admission in the medical record.

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- o Determine whether the medical records note the patient's admission and discharge time.
- o Observe whether the ASC correctly notes the time of admission for patients checking in and being discharged.
- o For cases reviewed that exceed the permitted expected time frame, ask the ASC to provide documentation indicating why it was reasonable to have expected that the time from admission to discharge would not exceed 24 hours. Acceptable evidence could include, but is not limited to, documentation that the procedure is one that Medicare has previously paid the ASC for, or other cases in the ASC involving the same procedure on similar patients that did not exceed the timeframe. ASCs may produce other evidence for surveyors to assess. Surveyors are not expected to know all of the surgical procedures covered by Medicare in an ASC, although they may obtain more information about this if they choose at http://www.cms.hhs.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS_1404_FC_ASC_AddAA_BB_DD1_DD2_EE.zip (This link requires a consent to use policies and then leads to a series of spreadsheets; the pertinent one is the ASC Addendum AA.) It is the responsibility of the ASC to demonstrate that the procedure is covered by Medicare when performed in an ASC.

FED - Q0020 - COMPLIANCE WITH STATE LICENSURE LAW

Title COMPLIANCE WITH STATE LICENSURE LAW

Type Condition

CFR 416.40

Regulation Definition

The ASC must comply with State licensure requirements.

Interpretive Guideline

State licensure requirements generally exist for both healthcare facilities and healthcare professionals. States vary considerably in their licensure requirements for entities that meet the Medicare definition of an ASC. Some States may not require separate licensure of these facilities, although all States require licensure of healthcare professionals providing services within the ASC. Some States may require separate licensure for some, but not all ASCs within their State; for example, in some States, ASCs that are operated as part of a physician single or group private practice may not require separate licensure as a healthcare facility. This condition requires that an ASC comply with whatever State licensure requirements are applicable to it.

In States where a separate facility license is required for a facility providing ambulatory surgical services, the ASC must have a current license that has not expired or been suspended or revoked. The ASC must also be in compliance with the State licensure requirements.

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Failure of the ASC to meet State licensure law may be cited when the State has made a determination of noncompliance and has also taken a final enforcement action as a result. Citation of licensure deficiencies may represent an initial step rather than a final action or determination by the State licensure authority. Additionally, the Federal survey of the ASC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an ASC had been assessed a civil monetary penalty by the State licensure authority in the previous year would not be grounds for citing the ASC for noncompliance with State licensure law, unless the State licensure authority indicates the ASC remains noncompliant.

If as a result of a State citation of an ASC for deficiencies in its compliance with licensure requirements the ASC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare supplier agreement as of the last date on which it provided services to Medicare beneficiaries, in accordance with §416.35(a)(3). The SA must advise the RO of the ASC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the ASC's State license has been revoked, suspended, or otherwise formally limited (e.g., admissions have been curtailed by the State), then the ASC is not in compliance with this condition and must be cited for a condition-level deficiency. Furthermore, survey of the rest of the CFCs cannot be completed, since the ASC is not providing surgical services to patients. The SA must advise the RO of such formal licensure enforcement actions and the RO will proceed with action to terminate the ASC supplier agreement, in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the ASC may not be in compliance with State licensure law, the information may be referred to the State licensure authority for follow-up.

While States vary as to the types of healthcare professionals that require licensure, all ASCs have physicians and nursing staff that require State licensure. It is the ASC's responsibility to verify that all ASC personnel who require a State license have a current license that has not expired or been suspended or revoked.

Survey Procedures

o Determine prior to the survey whether a facility license is required for the ASC. If there is access to State licensure files, review the ASC's State licensure status. Otherwise, ask to see the ASC's license.

o Review the ASC's documentation of all personnel required to be licensed under State or local laws or regulations. Check that the ASC has evidence that all personnel requiring licensure have current licenses in good standing.

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FED - Q0040 - GOVERNING BODY AND MANAGEMENT

Title GOVERNING BODY AND MANAGEMENT

Type Condition

CFR 416.41

Regulation Definition

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

Interpretive Guideline

The ASC must have a designated governing body that exercises oversight for all ASC activities. The governing body is responsible for establishing the ASC's policies, making sure that the policies are implemented, and monitoring internal compliance with the ASC's policies as well as assessing those policies periodically to determine whether they need revision. The regulation particularly stresses the responsibility of the governing body for:

- o direct oversight of the ASC's quality assessment and performance improvement (QAPI) program (see 72 FR 50472, August 31, 2007) and 73 FR 68714, November 18, 2008;
- o the quality of the ASC's healthcare services;
- o the safety of the ASC's environment; and
- o development and maintenance of a disaster preparedness plan.

In the case of an ASC that has one owner, that individual constitutes the governing body.

Although the governing body may delegate day-to-day operational responsibilities to administrative, medical, or other personnel, the ASC's governing body retains the ultimate responsibility for the overall operations of the ASC and quality of its services. The regulation also emphasizes the governing body's responsibilities in the areas of QAPI and disaster preparedness. Delegations of governing body authority should be documented in writing. The governing body is responsible for creating a safe environment where ASC patients can receive quality healthcare services. This means the governing body is not only responsible for adopting formal policies and procedures that govern all operations within the ASC, but also that it must take actions to ensure that these policies are implemented. Through its direct oversight and accountability for the ASC's QAPI program, it is expected that the ASC is better able to improve care being furnished to its patients. (See 72 FR 51472, August 31, 2007) When QA/PI citations are made related to 42 CFR 416.43, particularly Standard (e), citation of 42 CFR 416.41 should also be considered.

If condition-level deficiencies are cited related to multiple other ASC CfCs, with the result that the ASC does not provide quality healthcare or a safe environment, then it is also likely that the ASC is not complying with the governing body CfC.

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Survey Procedures

o Ask the ASC for information about its governing body. If there are questions about who constitutes the ASC's governing body, it may help to review the information the ASC reported in Section 6 of its CMS Form 855B application, identifying those individuals with ownership interest or managing control of the ASC.

o Ask the ASC how frequently the governing body meets and what are the typical items on its meeting agendas.

o Has the governing body delegated operational responsibility to a manager?

o Ask for an organizational chart of the ASC management. Ask who performs the following functions:

- Human Resources;
- Medical staff credentialing and granting of privileges;
- Management of surgical services;
- Management of nursing services;
- Management of pharmaceutical services;
- Management of laboratory (if applicable) and radiologic services;
- Management of the ASC's physical plant;
- Medical records maintenance;
- Infection control;
- Quality Assurance and Performance Improvement.

o Ask to see meeting minutes or other evidence that the ASC's policies and procedures have been formally adopted by the governing body.

o Ask to see meeting minutes or other evidence of how the governing body assures that its policies are implemented, and of how the governing body monitors internal compliance with and reassesses the ASC's policies. For example, is there any evidence of data collected and submitted to the governing body related to specific ASC policies?

o Ask to see meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the ASC's QA/PI program. See the discussion of §416.43 for more detail on the regulatory requirements related to QA/PI.

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FED - Q0041 - CONTRACT SERVICES

Title CONTRACT SERVICES

Type Standard

CFR 416.41(a)

Regulation Definition

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

Interpretive Guideline

ASCs may contract with third parties for provision of the ASC's services, including the ASC's environment. However, such a contract does not relieve the ASC's governing body from its responsibility to oversee the delivery of these ASC services. Given that many ASCs operate closely with a physician practice or clinic, or that some ASCs share space with other ASCs or other types of healthcare facilities operating at different times, use of a wide range of contract services may be common in ASCs. The ASC must assure that the contract services are provided safely and effectively. Contractor services must be included in the ASC's QAPI program.

For example:

- o If the ASC contracts for cleaning of the ASC, including its ORs/procedures rooms, the ASC's governing body is still responsible for the sanitary condition of the ASC and must exercise oversight over its contractor to assure that standard sanitary practices are employed.
- o If the ASC contracts for the provision of nursing services, the ASC remains responsible for assuring that all contract nurses are properly licensed and trained and oriented to perform their duties within the ASC. The ASC is responsible for the direction of nursing staff, regardless of whether they are employees or provided under contract.
- o If the ASC contracts for provision of anesthesia services, the ASC remains responsible for reviewing the credentials of all anesthesiologists and anesthesiologists providing anesthesia services and granting them privileges to do so.
- o If the ASC contracts (for example, with an associated adjacent physician practice) for provision of receptionist services, the ASC is responsible for assuring that such services are provided in a manner that complies with the patients' rights CfC requirements.
- o If the ASC contracts for medical records services, it must ensure that the contractor meets all requirements of the medical records CfC.

Survey Procedures

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- o Ask the ASC for a complete list of its currently contracted services.

- o Review the personnel files of contract personnel to determine, as applicable, their credentials, privileges, evidence of training, evidence of periodic evaluation, etc.

- o If the ASC is one that shares space (temporally separated) with other entities, ask the ASC whether it contracts or has some other formalized arrangement with any of those other entities for services when the ASC is in operation. If employees of an entity other than the ASC perform services while the ASC is in operation, and the ASC has no contract or other formal documentation of an arrangement with the other entity that governs the provision of such services, then the governing body fails to exercise its responsibility for the administration of the ASC's programs.

- o Ask the ASC how it assesses the safety and effectiveness of the services provided by each contractor, including how contractor services are incorporated into its QAPI program. Select several contractors from the list and ask for documentation of the most recent assessment of each by the ASC.

- o Ask the ASC management what process it uses to correct deficiencies in contracted services. Ask if there are any cases where it has identified deficiencies and taken corrective action, and if so, ask to see documentation of these cases.

FED - Q0042 - HOSPITALIZATION

Title HOSPITALIZATION

Type Standard

CFR 416.41(b)

Regulation Definition

- (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 periodically provide the local hospital with written notice of its operations and patient population served.

Interpretive Guideline

Guidance pending and will be updated in future release

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FED - Q0060 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Condition

CFR 416.42

Regulation Definition

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 Guideline

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.

FED - Q0061 - ANESTHETIC RISK AND EVALUATION

Title ANESTHETIC RISK AND EVALUATION

Type Standard

CFR 416.42(a)(1)

Regulation Definition

A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Interpretive Guideline

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient. The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement at 42 CFR 416.52(a)(1) for a history and physical assessment performed by a physician, although it is expected that the physician will review the materials from such

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pre-admission examination as part of the evaluation. Nevertheless, this requirement does constitute one component of the requirement at 42 CFR 416.52(a)(2) for a pre-surgical assessment upon admission. In those cases, however, where the comprehensive history and physical assessment is performed in the ASC on the same day as the surgical procedure, the assessment of the patient's procedure/anesthesia risk must be conducted separately from the history and physical, including any update assessment incorporated into that history and physical. See the interpretive guidelines for §§416.52(a)(1) & (2).

The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure. (Ideally, the ASC would conduct such an assessment prior to the patient's admission as well as immediately prior to surgery, but this is not specifically required by the regulations.)

The ASC's policies must address the basis or criteria used within the ASC in conducting these risk assessments, and must assure consistency among assessments.

The regulations do not specify the content or methodology to be employed in such assessments. As an illustrative example, an ASC might choose to incorporate consideration of a patient's ASA Physical Classification into its criteria. Although the American Society of Anesthesiologists did not create its ASA Physical Status Classification System for the purpose of predicting operative risk, this system has nevertheless been found to be useful in predicting morbidity and mortality in surgical patients and has been used by surgical facilities as a standard tool. This system classifies patients' physical status in 6 levels:

ASA PS I - normal healthy patient

ASA PS II - patient with mild systemic disease

ASA PS III - patient with severe systemic disease

ASA PS IV - patient with severe systemic disease that is a constant threat to life

ASA PS V - moribund patient who is not expected to survive without the operation

ASA PS VI - declared brain-dead patient whose organs are being removed for donor purposes

As the ASA PS level of a patient increases, the range of acceptable risk associated with a specific procedure or type of anesthesia in an ambulatory setting may narrow. An ASC that employed this classification system in its assessment of its patients might then consider, taking into account the nature of the procedures it performs and the anesthesia used, whether it will accept for admission patients who would have a classification of ASA PS IV or higher. For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.

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If a State establishes licensure limitations on the types of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the CfCs, then the ASC must conform to those State requirements. However, State requirements that would expand the types of procedures an ASC may offer beyond what is permitted under the CfCs are superseded by the Federal CfC requirements.

Survey Procedures

o Verify that there is evidence for every medical record in the survey sample of an assessment by a physician of the patient's risk for the planned surgery and anesthesia.

o Ask the ASC to provide you with its policies and procedures for assessment of anesthesia and procedural risk. Check to determine that the policies include the criteria the ASC's physicians are to use in making the assessments.

o Ask the ASC's leadership to demonstrate how they assure a consistent approach in the assessment.

Ask the ASC's leadership whether they can point to any cases where an assessment resulted in a decision not to proceed with the surgery. If there are no such cases, ask the ASC to explain how its patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk for every patient scheduled for surgery in the ASC - for example, do they use patient admission criteria that exclude higher risk patients? If so, ask to see those criteria.

o The survey sample should include cases where a patient died or needed to be transferred to a hospital; discuss the pre-surgical assessment of the patient in those cases, preferably with the physician who conducted the assessments, to explore the basis on which the patient was found to be suitable for the surgery and anesthesia.

FED - Q0062 - ANESTHETIC - DISCHARGE

Title ANESTHETIC - DISCHARGE

Type Standard

CFR 416.42(a)(2)

Regulation Definition

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

Interpretive Guideline

An evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC. American Society of Anesthesiology (ASA) guidelines do not define moderate or conscious sedation as anesthesia. While current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during, and after the

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for proper anesthesia recovery.

procedure by trained practitioners, a postanesthesia evaluation is not required.

The evaluation must be completed and documented by a physician or anesthetist, as defined at 42 CFR 410.69(b), i.e., a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant. See the discussion of §416.42(b) for more discussion of CRNA and anesthesiologist's assistant requirements.

ASCs would be well advised in developing their policies and procedures for postanesthesia care to consult recognized guidelines. For example, Practice Guidelines for Postanesthetic Care, *Anesthesiology*, Vol 96, No 3, March, 2002, provides the recommendations of the American Society of Anesthesiologists for routine postanesthesia assessment and monitoring, including monitoring/assessment of:

- o Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- o Cardiovascular function, including pulse rate and blood pressure;
- o Mental status;
- o Temperature;
- o Pain;
- o Nausea and vomiting; and
- o Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

Survey Procedures

- o Review the ASC's policies and procedures regarding postanesthesia recovery and evaluation to determine if they are consistent with the regulatory requirement. Determine whether the ASC is following its own policy.
- o Review a sample of medical records for patients who had surgery or a procedure requiring anesthesia to determine whether a postanesthesia evaluation was conducted for each patient.
- o Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.
- o Determine whether the evaluation was performed prior to the patient's discharge.

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FED - Q0063 - ADMINISTRATION OF ANESTHESIA

Title ADMINISTRATION OF ANESTHESIA

Type Standard

CFR 416.42(b) & (c)

Regulation Definition

b) Anesthetics must be administered by only:

(1) A qualified anesthesiologist; or
(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases where a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) State Exemption

(1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b) (2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

Interpretive Guideline

The ASC's policies and procedures must include criteria, consistent with State law governing scope of professional practice and other applicable State law, for determining the anesthesia privileges to be granted by the governing body to an eligible individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The ASC must specify the anesthesia privileges for each practitioner who administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and the ASC's policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

When granting anesthesia privileges to a physician who is not an anesthesiologist, the ASC's governing body must consider the practitioner's scope of practice, State law, the individual competencies, education, and training of the practitioner and the practitioner's compliance with the ASC's other criteria for granting physician privileges.

When an ASC permits operating physicians to supervise CRNAs administering anesthesia, the governing body must adopt written policies that explicitly provide for this.

A CRNA is defined in §410.69(b) as a "...registered nurse who: (1) is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to non-physician anesthetists; (3) has graduated from a nurse the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets the following criteria: (i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition." A CRNA may administer anesthesia in an ASC when under the supervision of the operating physician.

If the ASC is located in a State where the Governor has submitted a letter to CMS attesting that he or she has

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

consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a CRNA may administer anesthesia without physician supervision.

An anesthesiologist's assistant is defined in §410.69(b) as a "...person who - (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that - (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background." An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed, meaning the anesthesiologist is:

- o Physically present in the ASC; and
- o Prepared to immediately conduct hands-on intervention if needed.

A trainee who is a physician in training to be an anesthesiologist in a recognized graduate medical education program, or a student in a recognized nurse anesthesia or anesthesiologist's assistance educational program may administer anesthesia in an ASC when supervised by the operating physician, in the case of a nurse anesthetist trainee, or by an anesthesiologist, in the case of a physician trainee or an anesthesiologist's assistant trainee.

Survey Procedures

- o Prior to the survey, determine whether the State has exercised its CRNA physician supervision opt-out option.
- o Review the qualifications of individuals authorized to deliver anesthesia in the ASC, to determine whether they are consistent with the regulatory requirements.
- o Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.
- o If the ASC uses CRNAs, anesthesiologist's assistants or trainees, interview the ASC's leadership to determine how they are supervised. Do the medical records indicate that required physician supervision is provided?
- o When observing a procedure, look for evidence of appropriately trained practitioners with supervision as required by the regulations.

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FED - Q0064 - STANDARD LEVEL TAG FOR SURGICAL SERVICES

Title STANDARD LEVEL TAG FOR SURGICAL SERVICES

Type Standard

CFR 416.42

Regulation Definition

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 Guideline

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

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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:

- o 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;
- o 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
- o 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 together. 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), 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". 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

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preparations in anesthetizing locations indicates there is general consensus that the following fire risk reduction measures are appropriate:

- o 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;
- o 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;
- o 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
- o 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:

o §416.44(a)(1), concerning operating room design and equipment - for example:

- o 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;

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- o 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
- o Access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
- o §416.44(a)(2), concerning a separate recovery room;
- o §416.44(a)(3) and §416.51, concerning infection control, for example:
 - o The conformance to aseptic and, when applicable, sterile technique by all individuals in the surgical area;
 - o That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
 - o That operating room attire is suitable for the kind of surgical case performed;
 - o That equipment is available for rapid "emergency" high-level disinfection or, as applicable, sterilization of operating room materials;
 - o 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.
- o That, as applicable, temperature and humidity are monitored and maintained within accepted standards of practice; and
- o §§416.44(c) & (d), concerning emergency equipment and personnel - for example:
 - o That surgical staff are trained in the use of emergency equipment.

Survey Procedures: §416.42

- o Determine whether the ASC has policies and procedures that establish the criteria and process the governing

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body uses when granting surgical privileges to a physician. Ask for documentation that the governing body approved these policies and procedures.

- o 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).
- o 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.
- o 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.
- o Determine whether the ASC employs appropriate measures to reduce the risk of surgical fires.
- o 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.

FED - Q0080 - QUALITY ASSESSMENT AND PERFORMANCE

Title QUALITY ASSESSMENT AND PERFORMANCE

Type Condition

CFR 416.43

Regulation Definition

The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.

Interpretive Guideline

The QAPI CfC requires an ASC to take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers. The QAPI CfC presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASC's practices and getting to root causes of problems rather than just superficially addressing one problem at a time.

From a survey perspective, the focus of the QAPI condition is not on whether an ASC has any deficient practices, but rather on whether it has an effective, ongoing system in place for identifying problematic events, policies, or practices and taking actions to remedy them, and then following up on these remedial actions to determine if they were

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effective in improving performance and quality. QAPI programs work best in an environment that fixes problems rather than assigning blame.

For surveyors this can sometimes pose difficult challenges, because it requires a balancing act. ASCs are not relieved of their obligation to comply with all Medicare CfCs, and surveyors are obligated when they find evidence of violations of a CfC to cite accordingly. However, surveyors generally should avoid using the ASC's own QAPI program data and analyses as evidence of violations of other CfCs. For example, an ASC that identifies problems with infection control through its QAPI program and takes effective actions to reduce the potential for transmission of infection would be taking actions consistent with the QAPI CfC. Absent evidence independently collected by the surveyors of current noncompliance with the infection control CfC, it would not be appropriate for surveyors to use the infection control information in the ASC's QAPI program as evidence of violations of the infection control CfC. There can be egregious cases under investigation where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases should be the exception rather than the rule.

CMS does not prescribe a particular QAPI program; it provides each ASC with the flexibility to develop its own program. Each program must, however, satisfy the regulatory criteria:

- o Ongoing - i.e., the program is a continuing one, not just a one-time effort. Evidence of this would include, but is not limited to, things like collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.

- o Data-driven - i.e., the program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

Survey Procedures

When there is a team surveying the ASC, survey of the QAPI Condition should be coordinated by one surveyor.

FED - Q0081 - PROGRAM SCOPE; PROGRAM ACTIVITIES

Title PROGRAM SCOPE; PROGRAM ACTIVITIES

Type Standard

CFR 416.43(a), 416.43(c)(1)

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Regulation Definition

(a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

(c)(1) The ASC must set priorities for its performance improvement activities that -

- (i) Focus on high risk, high volume, and problem-prone areas.
- (ii) Consider incidence, prevalence, and severity of problems in those areas.
- (iii) Affect health outcomes, patient safety, and quality of care.

Interpretive Guideline

There are a variety of types of indicators that are currently in use for measuring and improving quality of healthcare. This is also a rapidly changing field, as interest and research in patient safety and healthcare quality measurement grows. As a result of a recommendation of a 1998 Presidential Advisory Commission, the National Quality Forum (NQF), a public-private not-for-profit membership organization, was created in 1999 to develop and implement a national strategy for healthcare quality measurement and reporting. Since then NQF has developed detailed recommendations for ways to promote and measure quality and patient safety, including in ASCs. The federal Agency for Healthcare Quality and Research (AHRQ) supports research assessing the effectiveness of care practices and procedures. A number of other organizations are also active in the field of healthcare quality improvement and patient safety. As a result, ASCs have many choices of indicators to use.

Indicators can be broken down into several types:

- o Outcomes indicators measure results of care; typical outcomes measures include risk-adjusted mortality rates, complication rates, healthcare-associated infection rates, length of stay, readmission rates, etc. In the ASC setting, outcomes measures might focus on things like complication rates, healthcare-associated infection rates, cases exceeding 24 hours, transfers to hospitals, wrong site surgeries, etc.
- o Process of care indicators measure how often the standard of care was met for patients with a diagnosis related to that standard. For example, in the ASC setting, measures might focus on the administration and time of prophylactic antibiotics.
- o Patient perception indicators measure a patient's experience of the care he/she received in the ASC. AHRQ sponsored development of one patient experience of care instrument, H-CAHPS, that CMS now uses in reporting on hospital quality. There may be similar patient survey instruments that could be used in the ASC setting.

The regulation at §416.43(a) requires that an ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must:

1. Be ongoing - i.e., the program is a continuing one, not just a one-time effort or occasional effort. Evidence that the ASC's program is ongoing would include, for example, collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.
2. Use quality indicators or performance measures associated with improved health outcomes in a surgical setting. The quality and safety indicators available differ in terms of the weight and type of evidence for their effectiveness in measuring quality. For some indicators there is compelling peer-reviewed research of an association with improved health outcomes. For others, typically process of care indicators, consensus among experts in the field suggests a strong association with improved quality of care. Indicators also differ in terms of how the data is collected, and how

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frequently the data should be collected.

For example, measures of how quickly an ASC produces error-free billing claims, while relevant to the ASC's financial performance and of interest to ASC governing bodies, have no direct relationship to the quality of care the ASC provides. On the other hand, a measure of the frequency with which the ASC administers antibiotic prophylaxis consistent with generally accepted standards of care would be related to improved health outcomes, i.e., prevention of surgical site infections. Likewise, an ASC could choose to collect data measuring its compliance with applicable National Quality Forum Safe Practices, or with applicable Centers for Disease Control and Prevention (CDC) infection control guidelines, or with guidelines issued by national professional societies, such as the American College of Surgeons, or with recommended practices developed by national accreditation organizations or other organizations specializing in healthcare quality improvement, such as the Institute for Healthcare Improvement. CMS does not prescribe a certain set of indicators/measures for ASCs to use, but ASCs must be able to demonstrate that the indicators they are tracking will enable them to improve outcomes for ASC patients.

The regulations at §416.43(c)(1) also require the ASC to set priorities in choosing its quality indicators/measures, because what is measured will determine where the ASC focuses its efforts to make changes that improve performance. For example, if the ASC does not track measures related to infection control, it will not be in a position to determine whether or not its infection control program is working well or poorly, and thus will not be in a position to improve it.

The ASC is required to focus on high risk, high volume, and problem-prone areas. It is required to consider, when selecting the measures/indicators that will shape its improvement activities in these areas, the following:

- o the incidence, i.e., the rate or frequency at which problems occur in the ASC related to area measured by the indicator. "Incidence" is a technical term used in epidemiology, referring to the frequency with which something, such as a disease, appears in a particular population or area. In disease epidemiology, the incidence is the number of newly diagnosed cases during a specific time period. Applying this concept in the ASC setting, as an example, the annual incidence of surgical site infections in an ASC would be the rate that results when dividing the number of such infections that occurred in a calendar year by the total number of surgical cases in the ASC during that same year. Likewise, the annual incidence of emergency transfers to a hospital would be the rate that results when dividing the number of such transfers by the total number of surgical cases during the same year;

- o the prevalence, i.e., how widespread something is in an ASC at a given point in time. "Prevalence" is also a technical term used in epidemiology, and is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time. In an ASC setting, for example, it would make little sense to

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employ measures related to prevalence of pressure ulcers among ASC patients, since the limited amount of time a patient typically spends in an ASC makes it unlikely that the ASC's care processes contributes to pressure ulcers. On the other hand a more appropriate measure might be periodic observation of the hand hygiene practices of all staff providing direct patient care, in order to assess the prevalence of good versus deficient practices; and

o the severity of problems. For example, any single instance of a transfer of a patient to a hospital represents a serious adverse, unplanned outcome of the surgical procedure, and it would be appropriate for an ASC to track and evaluate all such cases, due to their severity, even if they are low volume incidents.

Once having identified the quality indicators it will use, the ASC must collect and analyze data on these indicators.

3. Identify and reduce medical errors/adverse patient events. Although there is no single, standard definition of a medical error or adverse event, the Institute of Medicine created a series of definitions related to patient safety that are helpful in understanding the regulatory requirement:

"An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."

"An adverse event is an injury caused by medical management rather than the underlying condition of the patient."

"An adverse event attributable to error is a preventable adverse event."

Using these definitions, if an ASC performing orthopedic procedures operates on the right shoulder of a patient with a left shoulder rotator cuff injury requiring surgery, then the ASC has committed an error. The patient suffered an adverse event - i.e., the harm to the patient of undergoing surgery on the wrong shoulder, and presumably having to undergo yet another surgery on the correct shoulder. Because the ASC's error resulted in the adverse event, it is a preventable adverse event that could and should have been avoided.

Not every adverse event is the result of an error. For example, the standard of practice might call for use of a particular medication when certain indications are present. A patient might have an allergy to that medication that is unknown to the patient and the patient's physicians. The patient develops an allergic reaction to the medication, requiring further medical intervention to counteract the reaction. Due to the unknown nature of the patient's allergy, there was no error, even though there was an injury resulting from medical management. On the other hand, if the allergy had been documented in the patient's medical record and the medication had been administered anyway, this would constitute an error.

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Not every error results in an adverse event; for example, an ASC with two operating rooms might mix up the records of two ASC patients scheduled to have the same orthopedic procedure, e.g., foot surgery, on the same date, but on the opposite feet. This is an error. But the ASC employs a time-out procedure to verify the identity of the patients and site of the surgery and recognizes the error before surgery begins. The error did not result in an adverse event, but it was a near miss.

ASCs must track all patient adverse events, in order to determine through subsequent analysis whether they were the result of errors that should have been preventable, to reduce the likelihood of such events in the future. ASCs are also expected to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

ASCs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief period of time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the ASC to improve quality and safety.

Examples of ASC Quality/Patient Safety Indicators

The following information is based on the National Quality Forum's (NQF) consensus standards for ASCs, and is provided only as an illustration of several types of measures an ASC might choose to include in its QAPI program. An ASC is free to use different measures, so long as the measures it chooses meets the regulatory criteria. ASCs are also expected to develop additional measures related to infection control, for example to enable it to comply with the requirement at §416.51(b)(2) for its infection control program to be integrated into its QAPI program, and at §416.44(a)(3) to have a program to identify healthcare associated infections and report diseases as required under State law. Depending on the individual characteristics of the ASC, including problems it had experienced in the past, it may be necessary to track other additional indicators as well.

More information on these and other NQF ASC measures is available at:

<http://www.qualityforum.org/pdf/ambulatory/tbAMBALLMeasuresendorsed%2012-10-07.pdf>

- o Patient Burn - Percentage of ASC admissions experiencing a burn prior to discharge. Approximately 100 surgical fires occur each year nationally, in all surgical settings, with about 20 resulting in serious injuries to patients.

- o Prophylactic Intravenous Antibiotic Timing - Percentage of ASC patients who received appropriate antibiotics

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ordered for surgical site infection prophylaxis on time

o Hospital Transfer/Admission - Percentage of ASC admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC.

o Patient Fall - Percentage of ASC admissions experiencing a fall in the ASC.

o Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant - Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Survey Procedures

o Ask the ASC's leadership to describe the QAPI program, including staff responsibilities for QAPI and the quality/safety indicators being tracked.

o Ask what the rationale is for the particular indicators that the ASC has chosen to track. Are they based on nationally-recognized recommendations? If not, what evidence does the ASC have that the indicators it has chosen are associated with improvement in patient health outcomes and safety?

- At a minimum, do the indicators include cases of patients transferred from the ASC to a hospital?

- At a minimum, do the indicators include measures appropriate for surgery and infection control measures?

- At a minimum, does the ASC have a system for tracking adverse patient events?

o Ask the staff responsible for QAPI what the method and frequency is for data collection for each QAPI program indicator.

FED - Q0082 - PROGRAM DATA; PROGRAM ACTIVITIES

Title PROGRAM DATA; PROGRAM ACTIVITIES

Type Standard

CFR 416.43(b), 416.43(c)(2), 416.43(c)(3)

Regulation Definition

(b)(1) The program must incorporate quality indicator data,

Interpretive Guideline

Active Data Collection

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including patient care and other relevant data regarding services furnished in the ASC.

(b)(2) The ASC must use the data collected to -

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

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

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

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

The ASC must not only have identified a number of indicators or measures of quality and patient safety, but it must actively collect data related to those measures at the intervals called for by its QAPI program. Staff responsible for collection of the data should be trained in appropriate techniques to collect and maintain the data.

Data Analysis

Once having collected the data, the ASC must analyze it to monitor ASC performance, i.e., to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals, in order to avoid too much time elapsing before the ASC is able to detect problem areas. In the case of data related to adverse events, the ASC must use the data to analyze the cause(s) of the adverse events. Data collection and analysis must be conducted by personnel with appropriate qualifications to collect and interpret quantitative data. CMS does not expect ASCs to engage in sophisticated statistical modeling of data, but calculation of incidence rates should be within the skill set of individual(s) conducting the analysis. On the other hand, CMS does expect ASCs to conduct thorough analyses that focus on systemic issues. For example, if the ASC's adverse event tracking system identifies a medication error that resulted in serious injury to a patient, the ASC would not be taking the type of systems approach mandated under the QAPI regulations if it states that the event was caused by the staff member who administered the medication incorrectly, and that its method for improving performance was to fire that staff member. An acceptable analysis would look at the root causes that facilitated the error by the staff member: Were medications stored in a manner that increased the possibility of error? Were the physician's orders clearly written? Was the staff member appropriately trained? Is there any evidence of similar errors made by other staff members, including errors that did not result in adverse events? There are probably additional issues that should be investigated in order to fully understand the causes of the adverse event. Once there is a thorough analysis of these causes, the ASC would then be in a better position to identify improvement strategies that are appropriately designed to address the underlying causes.

The ASC may choose to use contractors for technical aspects of the QAPI program, including analysis of data, but the ASC is also expected to actively involve ASC staff in the program and the ASC's leadership retains the responsibility for the ongoing management of the program, even when a contractor is used.

Analysis of the monitoring data must be used to identify areas where there is room for improvement in the ASC's performance, as well as follow-up actions taken to improve performance. A good monitoring system, even in a good ASC surgical program, is likely to always find some areas of performance that are weaker than others. These identified areas of weakness present opportunities for the ASC to make changes in its systems, policies or procedures that result in improved patient care.

Implement Improvements/Preventive Strategies

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Once the ASC's analysis of its data has identified opportunities for improvement, the ASC must develop specific changes in its policies, procedures, equipment, etc., as applicable, to accomplish improvements in the identified areas of weakness. In particular, an ASC must implement preventive strategies designed to reduce the likelihood of adverse events throughout the ASC. For example, if an ASC has three operating or procedure rooms, and it has an adverse event in a case in one of these rooms that is attributable in part to a confusing storage of emergency medications, the ASC should review the set up in each of the rooms to ensure that the same problem does not occur elsewhere.

Sustaining Improvements

The ASC must also have a method to ensure that the improvements it makes are sustained over time. For example, if an ASC's QAPI program identifies problems with hand hygiene in ASC staff providing care to patients, the ASC must be able to demonstrate that whatever solution it adopted to address this problem continues to work over time. Generally this means that the ASC must collect data on indicators that measure staff hand hygiene on an ongoing basis.

Staff Training

The ASC is required to make all staff aware of the strategies it has adopted for prevention of adverse events. For example, all staff who are involved in the preparation of a patient for the surgical procedure, as well as in the conduct of the surgical procedure, must be familiar with the ASC's strategies for avoiding wrong patient, wrong site, wrong side, wrong procedure, wrong implant, adverse surgical events. All staff involved in the preparation and administration of injectable medications should be aware of standard safe injection practices designed to avoid the transmission of infectious disease. Staff should be encouraged to ask questions when they observe a practice, or receive an order, etc. that they believe might compromise patient safety or quality of care in the ASC.

Prospective ASCs Applying for Initial Certification in Medicare

A facility seeking initial certification as an ASC may not have been in operation long enough to demonstrate extensive data collection or the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place as well as to indicate when it expects to have sufficient data to begin analysis and what procedures it has put in place to consider the results of QAPI program analyses.

Survey Procedures

o Ask the ASC to show you examples of quality and adverse event data it is collecting. Is the ASC collecting data on all of the indicators/measures it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?

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o Ask the ASC who is responsible for the data collection and analysis, and what their qualifications are? In particular, ask the ASC how it determines the causes of adverse events - does the ASC stop with the immediate cause (staff error, equipment failure, etc.) or does it probe to discover the underlying root causes of the adverse events?

o If ASC staff handle these duties, do they have education or training that equips them to conduct analyses of the data?

o Ask the ASC to provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care. Ask how it evaluated whether the improvements were effective and sustained.

o Ask the ASC how it trains staff on ways to prevent adverse events from occurring.

o Ask ASC staff what they know about the ASC's QAPI program, focusing in particular on staff awareness of policies and procedures for preventing adverse events.

FED - Q0083 - PERFORMANCE IMPROVEMENT PROJECTS

Title PERFORMANCE IMPROVEMENT PROJECTS

Type Standard

CFR 416.43(d)

Regulation Definition

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

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

Interpretive Guideline

Every ASC must undertake one or more specific quality improvement projects each year. Larger ASCs with multiple ORs or procedure rooms, multiple types of surgical procedures offered, or high volume of cases are expected to undertake more or more complex projects. Furthermore, a highly complex improvement project might be of such scope that it could reasonably be the only project an ASC undertakes in a given year.

CMS does not specify particular projects that each ASC must undertake, but instead expects the projects to be based on the types of services the ASC furnishes, as well as other aspects of the ASC's operations. The requirement for annual projects does not mean that an ASC may not undertake a complex project that is expected to require more than one year in order to be completed.

The ASC must keep records on its performance improvement projects. Each project must, at a minimum, include an explanation of why the project was undertaken. The explanation must indicate what data collected in the ASC or based on recommendations of nationally recognized organizations leads the ASC to believe that the project's activities

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will actually result in improvements in patient health outcomes and safety in the ASC. For projects that are still underway, the ASC must be able to explain what activities the project entails, and how the impact of the project is being monitored. Unless the project has just begun, the ASC must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness. For projects that are completed, the ASC must be able to show documentation that explains what the results of the project were, and what actions, if any, the ASC took in response to those results.

Survey Procedures

o Ask the ASC to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.

o If a large, complex, or high volume ASC has only one project underway, is the scope of that project such that it is likely to have a significant impact on the ASC's quality of care or patient safety?

o Does the ASC's documentation indicate the rationale for undertaking each project? Does the ASC have data indicating it had a problem in the area targeted for improvement, or could the ASC point to recommendations from a nationally recognized expert organization suggesting the activities?

o Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the ASC what actions it took as a result of that information. If the project was successful, ask the ASC how it is sustaining the improvement.

FED - Q0084 - GOVERNING BODY RESPONSIBILITIES

Title GOVERNING BODY RESPONSIBILITIES

Type Standard

CFR 416.43(e)

Regulation Definition

The governing body must ensure that the QAPI program-

- (1) Is defined, implemented, and maintained by the ASC.
- (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.
- (3) Specifies data collection methods, frequency, and details.

Interpretive Guideline

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and implementation of every phase of the QAPI program. The governing body must assure that the ASC's QAPI program:

- o Is defined, in writing, for example in the minutes of a meeting where the governing body established the program;

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- (4) Clearly establishes its expectations for safety.
- (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

- o Is actually implemented, with written evidence of this implementation, as well as evidence of knowledge of the program by the ASC's staff;
- o Is implemented on an ongoing basis;
- o Employs quality and patient safety indicators that reflect appropriate prioritization, as required by §416.43(c);
- o Describes in detail the indicator data to be collected, how it will be collected, how frequently it will be collected;
- o Uses the data collected and analyzed to improve the ASC's performance;
- o Evaluates changes designed to improve the ASC's performance to determine whether they are effective, and takes appropriate actions to make further changes as needed;
- o Is designed to establish clearly the governing body's expectations that patient safety is a priority, not only by the tracking of all adverse events, but also by the program's processes for analyzing and making changes in ASC operations to prevent future such events; and
- o Has sufficient resources - i.e., the ASC's governing body must allocate sufficient and qualified staff (including consultants), staff time, information systems and training to support the program. Given the great variety in size and complexity among ASCs, the extent of resources required will vary as well. However, the resources dedicated to the QAPI program must be commensurate with the ASC's overall scope and complexity. The ASC must also be able to identify in detail the resources that it dedicates to the QAPI program.

Survey Procedures

- o Does the ASC's QAPI program include all of the essential elements described above?

- o Ask the ASC's leadership to explain how the governing body is involved in the QAPI program. Does the ASC's leadership display ready knowledge of the program's structure and activities. If a contractor is used for some portions of the program, does the ASC's leadership monitor closely the contractor's activities?

- o Is there evidence of governing body review of all elements of the QAPI program, e.g., meeting minutes?

- o Ask the ASC's leadership how it uses the program to improve performance. Ask for evidence of changes made as a result of QAPI program activities.

- o Ask the ASC's leadership for documentation of the details of the resources that are dedicated to the QAPI program. Is there evidence that these resources were actually made available as planned? For example, interview staff identified as having a role in the QAPI program to determine whether they actually perform QAPI functions, and for what percentage of their time. Is there evidence that planned data collections and analyses actually took place?

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FED - Q0100 - ENVIRONMENT

Title ENVIRONMENT

Type Condition

CFR 416.44

Regulation Definition

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

Interpretive Guideline

The ASC must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, safety from fire, emergency equipment and emergency personnel.

Survey Procedures

A surveyor trained in surveying for the applicable Life Safety Code standards must survey for compliance with the Safety from Fire Standard; the rest of the standards under this Condition are surveyed by Health surveyors.

FED - Q0101 - PHYSICAL ENVIRONMENT

Title PHYSICAL ENVIRONMENT

Type Standard

CFR 416.44(a)(1)

Regulation Definition

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

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 Guideline

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

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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

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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)

- o Verify the ASC's ORs meet applicable design standards.
- o Verify the ASC has the right kind of equipment in the ORs for the types of surgery it performs.
- o Verify the ASC has enough equipment, including surgical instrument sets, for the volume of procedures it typically performs.
- o 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.
- o Verify who within the ASC is responsible for equipment testing and maintenance.
- o 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.
- o 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.

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FED - Q0102 - SEPARATION

Title SEPARATION

Type Standard

CFR 416.44(a)(2)

Regulation Definition

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

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

Interpretive Guideline

The ASC is required to have both a waiting area and a recovery room, which must be separate from each other as well as other parts of the ASC. They may not be shared with another healthcare facility or physician office. (See the interpretive guidelines for §416.2 concerning sharing of physical space by an ASC and another entity.)

There must be a room within the ASC where patients recover immediately after surgery. A "room" consists of an area with at least semi-permanent walls from floor to ceiling separating it from other areas of the ASC. The recovery room must be equipped to allow appropriate monitoring of the patient's recovery. The type of equipment required depends on the type(s) of surgery performed in the ASC. The size of the recovery room must be commensurate with the number of ORs in the ASC and the expected volume of patients who will be in recovery simultaneously.

The recovery room may also be used for preoperative preparation of patients as well as for post-operative recovery, consistent with accepted standards of practice. Under no circumstances, however, may the recovery room also be used as a general waiting area for patients awaiting preoperative preparation or for people who accompany patients. Likewise, patients recovering from surgery may not be placed in a waiting room or area, unless they have already been discharged from the ASC and are, for example, waiting briefly while the adult who accompanied them brings a car to the ASC's entrance.

Consistent with accepted standards of practice, including infection control standards, and protection of patients' rights to privacy and confidentiality of their clinical information the ASC may permit individuals who accompany patients to be present in the recovery room during the patient's recovery from surgery.

Survey Procedures

- o Observe whether there is a separate room in which patients recover from their surgery, and whether it is appropriately equipped.

- o Observe whether there is a separate waiting area for visitors and patients who have not yet begun preoperative preparation.

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FED - Q0104 - SAFETY FROM FIRE

Title SAFETY FROM FIRE

Type Standard

CFR 416.44(b)(1)-(3)

Regulation Definition

Interpretive Guideline

(b) Standard: Safety from fire. (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

Guidance pending

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

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

FED - Q0105 - ALCOHOL-BASED HAND RUB DISPENSERS

Title ALCOHOL-BASED HAND RUB DISPENSERS

Type Standard

CFR 416.44(b)(4)

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Regulation Definition

Interpretive Guideline

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Guidance pending.

FED - Q0106 - SPRINKLER SYSTEM

Title SPRINKLER SYSTEM

Type Standard

CFR 416.44(b)(5)

Regulation Definition

Interpretive Guideline

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

Guidance pending.

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

FED - Q0107 - DOORS TO HAZARDOUS AREAS

Title DOORS TO HAZARDOUS AREAS

Type Standard

CFR 416.44(b)(6)

Regulation Definition

Interpretive Guideline

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.

Guidance pending.

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FED - Q0108 - BUILDING SAFETY

Title BUILDING SAFETY

Type Standard

CFR 416.44(c)

Regulation Definition

(c) Standard: Building Safety. Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guideline

Guidance pending.

FED - Q0109 - EMERGENCY EQUIPMENT

Title EMERGENCY EQUIPMENT

Type Standard

CFR 416.44(d)

Regulation Definition

(d) Standard: Emergency equipment. The ASC medical staff

Interpretive Guideline

Guidance pending.

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and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

- (1) Be immediately available for use during emergency situations.
- (2) Be appropriate for the facility's patient population.
- (3) Be maintained by appropriate personnel.

FED - Q0110 - EMERGENCY PERSONNEL

Title EMERGENCY PERSONNEL

Type Standard

CFR 416.44(e)

Regulation Definition

(e) Standard: Emergency personnel. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

Interpretive Guideline

Guidance pending.

FED - Q0111 - STANDARDS INCORPORATED BY REFERENCE

Title STANDARDS INCORPORATED BY REFERENCE

Type Standard

CFR 416.44(f)

Regulation Definition

(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the

Interpretive Guideline

No guidance.

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Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

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

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

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

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

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

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

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

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

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

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

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

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

(2) [Reserved]

FED - Q0120 - MEDICAL STAFF

Title MEDICAL STAFF

Type Condition

CFR 416.45

Regulation Definition

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

Interpretive Guideline

The organization of the medical staff is left to the discretion of the governing body, but however the staff is organized, the ASC must have an explicit, written policy that indicates how the medical staff is held accountable by the governing body. The policy must address all requirements in this condition. Medical staff privileges may be granted both to physician and non-physician practitioners, consistent with their permitted scope of practice in the State, as well as their training and clinical experience.

It is possible for an ASC to be owned and operated by one physician, who could be both the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases the physician owner must nevertheless implement a formal process for complying with all medical staff regulatory requirements.

Survey Procedures

Ask the ASC's leadership for its policy detailing how the governing body holds the medical staff accountable.

FED - Q0121 - MEMBERSHIP AND CLINICAL PRIVILEGES

Title MEMBERSHIP AND CLINICAL PRIVILEGES

Type Standard

CFR 416.45(a)

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Regulation Definition

Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

Interpretive Guideline

o All members of the ASC's medical staff and all clinicians granted medical staff privileges must be appointed to their position within the ASC by the ASC's governing body. They must be granted privileges by the governing body, in writing, that specify in detail the types of procedures they may perform within the ASC. It is not sufficient for the governing body to grant privileges to "perform surgery" or even to perform "orthopedic surgery." For example, an ASC that specializes in orthopedic surgery of various types must specify which types of procedures each surgeon is privileged to perform.

o The ASC's governing body must assure that medical staff privileges are granted only to legally and professionally qualified practitioners.

"Legally qualified" means the practitioner has a current license to practice within the State where the ASC is located, and that the privileges to be granted fall within that State's permitted scope of practice. The ASC must verify that each practitioner has a current professional license and document the license in the practitioner's file.

"Professionally qualified" means that the practitioner has demonstrated competence in the area for which privileges are sought. Competence is demonstrated through evidence of specialized training and experience, e.g., certification by a nationally recognized professional board.

o The governing body is also required to solicit the opinion of qualified medical personnel on the competence of applicants for privileges. The recommendation provided must be in writing, and should include a supporting rationale. The qualified medical personnel may be current members of the ASC's medical staff, but may also be physicians not practicing in the ASC. ASCs should consider seeking the recommendations of qualified outside physicians when they do not have appropriate expertise in-house to evaluate the competency of an applicant for privileges. This is particularly advisable when the ASC's governing body consists of one physician owner who is also the sole member of the medical staff. The ASC's governing body is not required to accept the recommendation provided by the qualified medical personnel to grant, deny, or restrict privileges to a practitioner. However, when the ASC's governing body makes a decision contrary to the recommendation, it is expected to document its rationale for doing so.

o The ASC should document the process by which the governing body grants medical staff privileges, including the documentation, or credentials, it reviews for each candidate, the criteria it uses in evaluating the candidate, how it selects the qualified medical personnel who make recommendations on the practitioner's qualifications, and whether and under what circumstances the governing body may make a privileging decision contrary to the recommendation of the qualified medical staff.

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Survey Procedures

o Ask the ASC's leadership to explain its process for granting clinical privileges.

o Review the personnel records for all medical staff who have been granted clinical privileges. There must at a minimum be documentation of:

- State licensure, registration, or state certification, as applicable;
- Certification by a specialty organization, as appropriate;
- Other training or pertinent experience;
- Evidence of a recommendation by qualified medical personnel concerning the practitioner's competence;
- The scope of the privileges granted to the practitioner; and
- If the governing body granted privileges against the recommendation of the qualified medical personnel, its rationale for doing so.

o Does the review of each practitioner's record provide evidence that they are legally and professionally qualified to exercise the privileges granted them by the ASC?

FED - Q0122 - REAPPRAISALS

Title REAPPRAISALS

Type Standard

CFR 416.45(b)

Regulation Definition

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 Guideline

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:

- o Review of the practitioner's current credentials; and

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- o 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)

- o Does the ASC periodically reappraise all practitioners granted clinical privileges?
- o Ask the ASC's leadership how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?
- o 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.
- o Do the reappraisals include evidence that data on the practitioner's practice within the ASC is considered along with the practitioner's credentials?

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FED - Q0123 - OTHER PRACTITIONERS

Title OTHER PRACTITIONERS

Type Standard

CFR 416.45(c)

Regulation Definition

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

Interpretive Guideline

Patient care responsibilities (which may or may not include formal medical staff privileges, but excluding nursing care services) may be assigned to licensed practitioners not meeting the definition of physician in §1861(r) of the Act. "Physician" is defined in §1861(r) (<http://www.cms.hhs.gov/regulations/>) of the Social Security Act as:

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

When an ASC uses licensed practitioners to provide patient care, other than nursing care, the ASC's governing body must approve written policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by other practitioners. The policies must address:

- o The specific types of clinical activities that each class of practitioner, e.g., Nurse Practitioner, Physician's Assistant, CRNA, will be eligible to perform. The ASC may not permit performance of any activities that are outside the licensed practitioner's permitted scope of practice under applicable State law;
- o The process by which the ASC exercises oversight over each class of practitioner. Depending on the practitioner's scope of practice, physician supervision of the practitioner may be required; in other cases oversight through collaborative practice with a physician or some other means may suffice.
- o The process and criteria for reviewing the qualifications of each individual practitioner before he/she is

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permitted to provide patient care;

o The process, criteria and frequency for evaluating the performance in providing clinical services by practitioners other than physicians. Evaluations must take place at regular intervals specified in the ASC's policy.

Survey Procedures

Determine whether the ASC uses licensed practitioners other than physicians to provide care, other than nursing care, within the ASC. If it does:

- Ask to see the ASC's policy governing the oversight and evaluation of practitioners other than physicians. Does the policy address all required issues?

- Review the personnel files for each licensed practitioner who is not a physician providing patient care in the ASC. Does each file contain evidence of the practitioner's qualifications, consistent with the ASC's policy? Does each file contain evidence of periodic evaluation of the practitioner's performance?

FED - Q0140 - NURSING SERVICES

Title NURSING SERVICES

Type Condition

CFR 416.46

Regulation Definition

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

Interpretive Guideline

The ASC must ensure that the nursing service is directed under the leadership of an RN. The ASC must have documentation that it has designated an RN to direct nursing services.

There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all ASC patients are met. This implies that there is ongoing assessment of patients' needs for nursing care, and that identified needs are addressed. The number and types of nursing staff needed will depend on the volume and types of surgery the ASC performs.

Survey Procedures

o Ask the ASC's leadership to identify the person responsible for the direction of nursing services within the ASC. Is that person an RN?

o Review the staffing available for patients undergoing surgery during the survey; are there sufficient staff to address

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each patient's nursing needs?

o Do nursing staff have the appropriate qualifications for the tasks they are asked to perform?

FED - Q0141 - ORGANIZATION AND STAFFING

Title ORGANIZATION AND STAFFING

Type Standard

CFR 416.46(a)

Regulation Definition

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

Interpretive Guideline

Every nurse in the ASC must have clearly delineated assigned responsibilities for providing nursing care to patients. These assignments must be in writing; job descriptions would suffice for a general articulation of the responsibilities for each nurse. Individual patient assignments on a given day must be documented clearly in the assignment sheet.

The ASC's nursing services must be consistent with recognized standards of practice. "Recognized standards of practice" means that the services provided are consistent with State laws governing nursing scope of practice, as well as with nationally recognized standards or guidelines for nursing care issued by organizations such as the American Nurses Association, the Association of Operating Room Nurses, etc.

An RN with specialized training or experience in emergency care must be available to provide emergency treatment whenever there is a patient in the ASC. "Available" means on the premises and sufficiently free from other duties that the nurse is able to respond rapidly to emergency situations. In accordance with the requirements at §416.44(d), the ASC must have personnel present who are trained in the use of the required emergency equipment specified at §416.44(c) and in cardiopulmonary resuscitation whenever there is a patient in the ASC. The RN(s) designated to provide emergency treatment must be able to use any of the required equipment, so long as such use falls within an RN's scope of practice. ASC's would be well advised to assure that the RN(s) designated to provide emergency treatment have training in advanced cardiac life support interventions.

Survey Procedures

o Are the general responsibilities for each ASC nurse for providing patient care clearly documented?

o Ask nursing staff to explain what their duties for the day of the survey are; can they articulate clearly what their patient care responsibilities are?

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o Ask the ASC to explain how it evaluates the nursing care provided in the ASC for conformance to acceptable standards of practice.

o Ask the ASC to identify the RN(s) who are available for emergency treatment. Is there documentation of their qualifications to provide emergency treatment? Do staff in the ASC know which RN(s) (as well as medical staff) to call when a patient develops an emergency?

o Ask the ASC for evidence that one or more RN(s) are readily available to provide emergency treatment. How do they assure that an RN can leave their current task to respond to the emergency without putting another patient at risk of harm?

FED - Q0160 - MEDICAL RECORDS

Title MEDICAL RECORDS

Type Condition

CFR 416.47

Regulation Definition

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

Interpretive Guideline

The ASC must have a complete, comprehensive and accurate medical record for each patient. Material required under other Conditions, such as the history and physical examination or documentation of allergies to drugs and biologicals required under §416.52, must be incorporated into the medical record in a timely fashion. The ASC must use the information contained in each medical record in order to assure that adequate care is delivered to each ASC patient. In accordance with the provisions of the Patients' Rights Condition at §416.50(d), the ASC must ensure the confidentiality of each patient's medical record.

Survey Procedures

Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

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FED - Q0161 - ORGANIZATION

Title ORGANIZATION

Type Standard

CFR 416.47(a)

Regulation Definition

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

Interpretive Guideline

The ASC must have a documented system that enables it to systematically develop a unique medical record for each patient, permit timely access to the medical record to support the delivery of care, and to store records. Records may exist in hard copy, electronic format, or a combination of the two media.

The regulation does not prescribe how long a closed record is to be maintained by the ASC, but many States have laws governing retention of medical records.

Survey Procedures

- o Review the ASC's medical record policy and interview the person responsible for the medical records to ascertain that the system is structured appropriately.
- o If the ASC employs a fully or partially electronic medical record system, ask clinical personnel to demonstrate how they use the system, in order to determine whether they are able to make entries and access needed information in order to support the provision of care.
- o Determine that closed records are retained in accordance with applicable State law.
- o Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

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FED - Q0162 - FORM AND CONTENT OF RECORD

Title FORM AND CONTENT OF RECORD

Type Standard

CFR 416.47(b)

Regulation Definition

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

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

Interpretive Guideline

Guidance pending and will be updated in future release.

FED - Q0180 - PHARMACEUTICAL SERVICES

Title PHARMACEUTICAL SERVICES

Type Condition

CFR 416.48

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Regulation Definition

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

Interpretive Guideline

Drugs and biologicals used within the ASC must be provided safely and in an effective manner, consistent with generally accepted professional standards of pharmaceutical practice and with the requirements specified in the Standards within this Condition.

The ASC must designate a specific licensed healthcare professional to provide direction to the ASC's pharmaceutical service. That individual must be routinely present when the ASC is open for business, but continuous presence is not required, particularly when the ASC is open for longer periods of time to accommodate the recovery of patients for up to 24 hours. Ideally the ASC should have available a pharmacist who provides oversight or consultation on the ASC's pharmaceutical services, but this is not required by the regulation, unless the ASC is performing activities which under State law may only be performed by a licensed pharmacist.

Survey Procedures

- o Ask the ASC's leadership for evidence that a qualified individual has been designated to direct pharmaceutical services in the ASC.

- o Ask how often and for how long this individual is on-site at the ASC. Determine whether there is any documentation indicating that the individual is providing active direction and oversight to the program.

FED - Q0181 - ADMINISTRATION OF DRUGS

Title ADMINISTRATION OF DRUGS

Type Standard

CFR 416.48(a)

Regulation Definition

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

Interpretive Guideline

Drugs and biologicals used within the ASC must be administered to patients in accordance with formal policies the ASC has adopted, and those policies and the ASC's actual practices must conform to acceptable standards of practice for medication administration.

"Accepted professional practice" and "acceptable standards of practice" mean that drugs and biologicals are handled and provided in the ASC in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals. This would include organizations such as the National Association of Boards of Pharmacy, the Institute for Safe Medication Practices, the

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American Society of Health-System Pharmacists, etc.

The ASC must have policies and procedures designed to promote medication administration consistent with acceptable standards of practice. The policies and procedures should address issues including, but not limited to:

- o A physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.
- o Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.
- o Avoiding preparation of medications too far in advance of their use. For example, while it may appear efficient to pre-draw the evening before all medications that will be used for surgeries scheduled the following day, this practice may, depending on the particular drug or biological, promote loss of integrity, stability or security of the medication.
- o Any pre-filled syringes must be initialed by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date.
- o Employing standard infection control practices when using injectable medications.

There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs. The ASC's policies and procedures should also address the following:

- o Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
- o Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- o Records to trace the movement of scheduled drugs throughout the ASC.
- o The licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is

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maintained and reconciled.

- o The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- o All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- o The ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

Survey Procedures

- o Is there evidence in the medical records reviewed that there is an order, signed by a physician or other qualified practitioner, for every drug or biological administered to the patient?

- o Are drugs or biologicals administered only by nurses or other qualified individuals, or under the supervision of nurses or other qualified individuals, as permitted under Federal or State law and the ASC's policy?

- o Determine whether medications are properly labeled, stored, and have not expired.

- o Using the infection control survey tool, determine whether the ASC employs safe injection practices.

- o If the ASC uses scheduled drugs:

- Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

- Review the records to determine that they trace the movement of scheduled drugs throughout the ASC.

- Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction or return to the manufacturer. Determine if this system provides documentation on scheduled drugs in a readily

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retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- Determine if the licensed health care professional who is in charge of the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the ASC's system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

FED - Q0182 - ADMINISTRATION - ADVERSE REACTIONS

Title ADMINISTRATION - ADVERSE REACTIONS

Type Standard

CFR 416.48(a)(1)

Regulation Definition

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

Interpretive Guideline

Every adverse reaction to a drug or biological that a patient experiences while in the ASC must be reported promptly to the physician on the ASC's medical staff who is responsible for that patient. This permits that physician to assess the patient in a timely manner and determine whether additional treatment is required in order to counteract the adverse reaction.

All adverse drug reactions experienced by patients while in the ASC must be documented in the patient's medical record.

The ASC's policies and procedures must incorporate these requirements and ASC staff must be aware of and comply with them.

Survey Procedures

o Interview clinical staff to ask them what steps they would take if a patient experiences an adverse reaction to a drug? Are staff aware of the requirement to promptly report this information to the physician on the ASC's medical staff who is responsible for the patient?

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o Look for documentation of adverse drug reactions in the sample of records selected for review. If no adverse drug reactions are noted, ask ASC staff whether they recall any patients having adverse drug reactions, and if so, whether they could pull a medical record containing documentation of an adverse drug reaction.

o Determine whether the ASC's policies and procedures address adverse drug reactions and are consistent with the regulatory requirements.

FED - Q0183 - BLOOD AND BLOOD PRODUCTS

Title BLOOD AND BLOOD PRODUCTS

Type Standard

CFR 416.48(a)(2)

Regulation Definition

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

Interpretive Guideline

If the ASC ever administers blood or blood products to patients, it may permit only a physician on the ASC's medical staff or an RN working in the ASC to administer blood and blood products. The ASC's policies and procedures must specifically address this requirement, unless the ASC does not keep blood or blood products on hand and never administers such products to ASC patients.

Survey Procedures

Determine whether the ASC administers blood or blood products to patients. If yes,

- Determine from the record review whether anyone other than a physician on the ASC's medical staff or an ASC RN administered the blood or blood product.

- Determine whether the ASC's policies specifically restrict administration of blood and blood products to a physician or RN.

FED - Q0184 - VERBAL ORDERS

Title VERBAL ORDERS

Type Standard

CFR 416.48(a)(3)

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Regulation Definition

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

Interpretive Guideline

Orders for drugs and biologicals that are transmitted as oral, spoken communications between the prescribing physician and the ASC's nursing staff, delivered either face-to-face or via telephone, commonly called "verbal orders," must be followed by a written order that is signed by the prescribing physician.

CMS expects ASC policies and procedures for verbal orders to include a read-back and verification process whereby the nurse receiving the order repeats it back to the prescribing physician, who verifies that it is correct. When administering a drug or biological per a verbal order, the nurse should include in the medical record entry covering the administration of the drug or biological a note that it was prescribed orally, indicating the name of the prescribing physician.

The prescribing physician must sign, date and time the written order in the patient's medical record confirming the verbal order. This should be done as soon as possible after the verbal order is issued.

In the ASC setting medications prescribed for patients in recovery present a particular area of vulnerability in terms of the potential failure to follow-up a verbal order with a written order signed by the prescribing physician; careful attention must be given to compliance with the regulatory requirement for medications administered during recovery room.

Survey Procedures

o Does the ASC have policies and procedures addressing verbal orders? Does it require the prescribing practitioner to sign, date, and time a written order as soon as possible after issuing the verbal order?

o Do the ASC's policies and procedures for verbal orders include a "read back and verify" process where the nurse who receives the order repeats it back to the prescribing physician to verify that the order was understood accurately?

o Ask ASC nursing staff how they handle verbal orders. Does their practice conform to the regulatory requirements? Do they use a read-back and verify process?

o Is there evidence in the medical records reviewed that each verbal order was followed by a written order signed by the prescribing physician?

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FED - Q0200 - LABORATORY AND RADIOLOGIC SERVICES

Title LABORATORY AND RADIOLOGIC SERVICES

Type Condition

CFR 416.49

Regulation Definition

Interpretive Guideline

Lack of substantial compliance with either the laboratory or the radiologic standard within this condition could provide a basis for citing a condition-level deficiency.

FED - Q0201 - LABORATORY SERVICES

Title LABORATORY SERVICES

Type Standard

CFR 416.49(a)

Regulation Definition

If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter.

Interpretive Guideline

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

- o A well-defined arrangement (need not be contractual) with outside services;
- o Laboratory services that are provided by the ASC;
- o Routine procedures for requesting lab tests; and
- o Language that requires the incorporation of lab/radiological reports into patient records.

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

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FED - Q0202 - RADIOLOGIC SERVICES

Title RADIOLOGIC SERVICES

Type Standard

CFR 416.49(b)(1)

Regulation Definition

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

Interpretive Guideline

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)

o 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?

FED - Q0203 - RADIOLOGIC SERVICES

Title RADIOLOGIC SERVICES

Type Standard

CFR 416.49(b)(1)

Regulation Definition

[Radiologic services...]

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

Interpretive Guideline

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

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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:

- o Adequate shielding for patients, personnel and facilities;
- o Labeling of radioactive materials, waste, and hazardous areas;
- o Transportation of radioactive materials between locations within the hospital;

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- o Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- o Testing of equipment for radiation hazards;
- o Maintenance of personal radiation monitoring devices;
- o Proper storage of radiation monitoring badges when not in use;
- o Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- o Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- o Methods of identifying pregnant patients.

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

Survey Procedures §482.26(b)(1)

- o Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the hospital.
- o Verify that hazardous materials are stored properly in a safe manner.
- o 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.

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Survey Procedures §482.26(b)(2)

- o 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.
- o 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)

- o 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.
- o Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.
- o 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.

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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.

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Survey Procedures §482.26(d)(2)

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

Survey Procedures: §416.49(b)(1)

- o 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?
- o 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?

FED - Q0204 - RADIOLOGIC SERVICES

Title RADIOLOGIC SERVICES

Type Standard

CFR 416.49(b)(2)

Regulation Definition

(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 Guideline

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

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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)

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

FED - Q0219 - PATIENT RIGHTS

Title PATIENT RIGHTS

Type Condition

CFR 416.50

Regulation Definition

Condition for Coverage - Patient Rights

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guideline

The ASC must inform each of its patients, or the patient's representative or surrogate in the case of minor patients or other situations where there is a designated representative for the patient, of their rights as an ASC patient. Further, all of the ASC's policies, procedures and actions must be consistent with the protection of the patients' rights articulated in this Condition. Further, the ASC must actively promote the patient's exercise of their rights.

In addition, the ASC must ensure that the written notice of patient rights is posted in one or more places where it is likely to be seen by patients waiting for treatment, or the patient's representative or surrogate, if applicable. Such areas include, but are not limited to, waiting rooms or pre-operative preparation areas where patients are awaiting care. Notices must be posted in at least one area. Whether the ASC must post more than one notice depends on the size and physical layout of the areas where notices are posted. The determining factor is whether the notice(s) are posted in a manner that all patients (or their representatives or surrogates, as applicable) are likely to see the notice.

The patient's representative or surrogate is an individual designated by the patient, in accordance with applicable State law, to make health care decisions on behalf of the individual or to otherwise assist the patient during his/her stay in the ASC. Designation may be in writing, as in an advance directive or medical power of attorney, or may be

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oral (verbal). Written designation may occur before the patient presents to the ASC, or during the ASC registration process. Oral designation may take place at any time during the patient's visit in the ASC. The patient's representative or surrogate includes, but is not limited to, an individual who could be a family member or friend who accompanies the patient. Depending on the designation the patient has made, the patient's representative or surrogate may make all health care decisions for the patient during his/her ASC visit, or may act in a more limited role, for example, as a liaison between the patient and the ASC to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the ASC staff. If a patient is unable to fully communicate directly with the ASC staff, then the ASC may give patient rights information to the patient's representative or surrogate.

Survey Procedures:

When there is a team surveying the ASC, survey of the Patients' Rights Condition should be coordinated by one surveyor. However, each surveyor, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Patient's Rights regulatory requirements. It is particularly important for the surveyor who will be following one or more patients from the start of their case to discharge to be observing how the ASC's actions protect and promote those patients' exercise of their rights.

- o Determine whether the ASC provides patients (or their representatives or surrogates, as applicable), with notice of their rights, consistent with the standards under this condition.
- o Determine whether the ASC promotes the patients' exercise of their rights (or their representatives or surrogates, as applicable), consistent with the standards under this condition.
- o Review posted notices to determine if they contain the same information as the individual written notice provided to patients or their representatives/surrogates, as required under § 416.50(a). Deficiencies related to posting of the notice are to be cited using tag -Q0219.

FED - Q0220 - NOTICE - POSTING

Title NOTICE - POSTING

Type Standard

CFR 416.50

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Regulation Definition

... The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guideline

Interpretive Guidelines: (standard-level citation only)

Since the condition concerning posting the written notice does not have a counterpart in a standard within the patient rights condition, a second tag is provided for this portion of the condition for citations at the standard level. Deficiencies related solely to posting of the notice must be cited at the standard level, using tag Q-0220. The condition-level tag, Q-0219, must be cited whenever the manner and degree of noncompliance on the part of an ASC represents substantial noncompliance.

Survey Procedures:

o Observe waiting rooms and pre-operative areas where patients await care to see if notice of patient rights is posted in a manner where all patients awaiting care are likely to see a notice. Ensure that the notices are posted in conspicuous locations in the waiting rooms, pre-operative preparation areas, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area use by every ASC patient. Deficiencies related to posting of the notice are to be cited using tag -Q0219.

FED - Q0221 - NOTICE OF RIGHTS

Title NOTICE OF RIGHTS

Type Standard

CFR 416.50(a)

Regulation Definition

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 Guideline

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

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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:

- o Address all of the patient's rights under this Condition.

- o 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

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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)

- o 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?
- o 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:
- o Does the notice address all of the patients' rights listed in this Condition?
- o Does the notice provide the required information about where to file complaints or how to contact the Medicare Ombudsman?
- o 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?
- o 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.
- o Does the ASC provide all patients with verbal and written notice of their rights prior to the start of the surgical procedure?

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- o 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?

- o Ask patients to tell you how, when and what the ASC has told them about their rights.

FED - Q0222 - NOTICE OF RIGHTS - POSTING

Title NOTICE OF RIGHTS - POSTING

Type Standard

CFR 416.50(a)(1)(i)

Regulation Definition

(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 Guideline

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.

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Survey Procedures: §416.50(a)(1)(i)

- o 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.

- o Observe notices to see that each notice contains all required information.

FED - Q0223 - NOTICE - PHYSICIAN OWNERSHIP

Title NOTICE - PHYSICIAN OWNERSHIP

Type Standard

CFR 416.50(b)

Regulation Definition

The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

Interpretive Guideline

An ASC that has physician owners or investors must provide written notice to the patient, the patient's representative or surrogate, prior to the start of the surgical procedure, that the ASC has physician-owners or physicians with a financial interest in the ASC. CMS considers the disclosure of physician financial interest or ownership to be part of the overall "patient rights information" that is now required to be given prior to the start of the procedure. 42 CFR Part 420 provides definitions and requirements concerning ownership and control of Medicare-participating providers and suppliers. Surveyors are not expected to have expert knowledge of what constitutes ownership and control, but ASCs are required to comply with the provisions of Part 420. ASCs that meet the physician ownership and control threshold specified in 42 CFR Part 420 must disclose their physician ownership to patients and provide them with a list of physicians who have a financial interest or ownership in the ASC. The intent of this disclosure requirement is to assist the patient in making an informed decision about his or her care by making the patient, or the patient's representative or surrogate, aware when physicians who refer their patients to the ASC for procedures, or physicians who perform procedures in an ASC also have an ownership or financial interest in the ASC.

The written notice must disclose, in a manner designed to be understood by all patients, that physicians have an ownership or financial interest in the ASC. Information should be provided in a manner that is not only technically correct, but also easily understood by persons not familiar with financial statements, legal documents or technical language. The ASC should also be aware of the age and the cognitive abilities of its patients in developing its written notice. (72 FR 50475, August 31, 2007)

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Survey Procedures:

o Ask the ASC whether it has reported in accordance with 42 CFR Part 420 to the Medicare program whether the ASC has any physicians with ownership/financial interests. (Surveyors are not required to make an independent determination regarding whether an ASC has physicians with ownership or financial interests.) If the answer is yes, then the ASC is required to comply with the requirement for disclosure to patients. If the ASC's response is no, then the ASC has no disclosure requirement and the surveyor does not have to investigate further.

o If the ASC indicates it has physicians with ownership/financial interests in the ASC:

- Does the ASC have policies and procedures in place to make the required disclosures to patients? Are the policies and procedures consistent with the regulatory requirements?

- Does the ASC provide a written notice of disclosure to all patients prior to the start of the surgical procedure, including a list of physicians with financial interests or ownership in the ASC?

o Interview ASC staff to assess their knowledge and understanding of the physician ownership notice requirements, including the ASC's process for delivering the notice.

o Interview patients to ask them whether they were aware that the ASC has physician owners/investors. Ask them if they recall getting a written notice about this prior to the start of their surgical procedure.

FED - Q0224 - ADVANCED DIRECTIVES

Title ADVANCED DIRECTIVES

Type Standard

CFR 416.50(c)(1)(2)(3)

Regulation Definition

The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies

Interpretive Guideline

Information on Advance Directives

An advance directive is a written instruction, such as a living will or durable power of attorney for healthcare, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of

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on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.

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

healthcare when the individual who has issued the directive is incapacitated. (See 42 CFR 489.100.)

Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, subject to the ASC's limitations on the basis of conscience. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process.

The facility must provide the patient or the patient's representative, as appropriate, the following information in writing, prior to the start of the surgical procedure:

- o Information on the ASC's policies on advance directives;
- o A description of the applicable State health and safety laws. (Note that CMS does not determine whether this description is accurate. State Survey Agencies are responsible for making this accuracy determination.); and
- o If requested, official State advance directive forms, if such exist.

The ASC must include in the information concerning its advance directive policies a clear and precise statement of limitation if the ASC cannot implement an advance directive on the basis of conscience or any other specific reason that is permitted under State law. A blanket statement of refusal by the ASC to comply with any patient advance directives is not permissible. However, if and to the extent permitted under State law, the ASC may decline to implement elements of an advance directive on the basis of conscience or any other reason permitted under State law if it includes in the information concerning its advance directive policies a clear and precise statement of limitation. A statement of limitation must:

- o Clarify any differences between ASC-wide conscience objections and those that may be raised by individual ASC staff;
- o Identify the state legal authority permitting such objection; and
- o Describe the range of medical conditions and procedures affected by the objection

For example, the ASC's notice of limitation could, if permitted by State law, indicate that it would always attempt to resuscitate a patient and transfer that patient to a hospital in the event of deterioration.

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The patient may wish to delegate his/her right to make informed decisions to another person, even though the patient is not incapacitated. To the extent permitted by State law, the ASC must respect such delegation. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney, or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate, so that informed healthcare decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the ASC should also provide that information to the patient.

The right to make informed decisions presumes that the patient, or the patient's representative or surrogate, has been provided information about the patient's health status, diagnosis and prognosis. It includes providing consent to the surgical procedure(s) to be performed in the ASC. The patient, or the patient's representative or surrogate, must 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 about care in the ASC. In many cases, the informed consent may take place in a physician office outside the ASC and prior to the patient's visit to the ASC. Nevertheless, the ASC is responsible for ensuring an informed process is in place for each patient. (See discussion of fully informing the patient under §416.50(e)(iii).)

Documentation of Advance Directives

The ASC must document in the patient's current medical record, i.e., the record for the current ASC visit, whether or not the patient has executed an advance directive. This documentation must be placed in a prominent part of the medical record where it will be readily noticeable by any ASC staff providing clinical services to the patient. The documentation requirement applies, even if the ASC is unable to comply with the patient's advance directive on the basis of conscience or a State law limitation.

If the patient with an advance directive is transferred from the ASC to another healthcare facility, e.g., if there is an emergency transfer to a hospital, the ASC must ensure that a copy of the patient's advance directive is provided with the medical record when the patient is transferred.

The ASC should provide education to its staff concerning the facility's policies and procedures on advance directives.

Survey Procedures:

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- o Review the ASC's policies and procedures related to the advance directive requirements. Do they conform to the regulatory requirements?
- o Ask to see a copy of the written notice of the ASC's advance directive policies and applicable State law. Does it contain all required information? If there is a statement of limitations based on conscience or State law, does it include all required information?
- o If the State has an official advance directive form, ask the ASC to demonstrate how it provides these forms upon request to patients.
- o Ask the ASC how it documents that required advance directive information is provided to the patient prior to the start of the surgical procedure. Review each record in the survey sample to determine if there is evidence that the information was provided to the patient or the patient's representative prior to the start of the surgical procedure.
- o Review each record in the survey sample to determine if advance directive information was provided prior to the start of the surgical procedure.
- o Does the ASC advise patients, or the patient's representative or surrogate, of their right to make informed decisions about their care in the ASC?
- o Review each record in the survey sample to determine if information is prominently displayed as to whether or not there is an advance directive in effect for the patient. Is the information displayed in a manner such that patients with advance directives can be readily distinguished from patients without an advance directive?
- o Determine to what extent the ASC educates its staff regarding advance directives and promoting informed decisions. Does the ASC have a training class or any educational materials available for the staff regarding advance directives and informed patient decision-making? Interview staff to determine their knowledge of the advance directives of the patients in their care.

FED - Q0225 - SUBMISSION AND INVESTIGATION OF GRIEVANCES

Title SUBMISSION AND INVESTIGATION OF GRIEVANCES

Type Standard

CFR 416.50(d)(4),(5), & (6)

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Regulation Definition

The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

- (1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.
- (2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.
- (3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

Interpretive Guideline

What is a grievance?

A "patient grievance" is a formal or informal written or verbal complaint that is made to the ASC by a patient or a patient's representative or surrogate, regarding a patient's care (when such complaint is not resolved at the time of the complaint by the staff present), abuse, neglect, or ASC compliance issues.

o A complaint from someone other than a patient or a patient's representative or surrogate is not a grievance.

o A complaint that is presented to the ASC's staff and resolved at that time is not considered a grievance; the grievance process requirements do not apply to such complaints. For example, a complaint that discharge instructions are unclear may be resolved relatively quickly before the patient is discharged, and would not usually be considered a "grievance."

If a patient care complaint cannot be resolved at the time of the complaint by the staff present, is postponed for later resolution, is referred to other staff for later resolution, requires an investigation, and/or requires additional actions for resolution, the complaint is then considered a grievance for purposes of these requirements.

Billing issues are not usually considered grievances for the purposes of this grievance requirement.

Although complaints may be both written and verbal, a written complaint is always considered a grievance. This includes written complaints from a current patient, a released/discharged patient, or a patient's representative or surrogate regarding the patient care provided, abuse or neglect, or the ASC's compliance with the CfCs. For the purposes of this requirement, an email or fax is considered written.

Information obtained from patient satisfaction surveys conducted by the ASC usually is not considered a grievance. However, if an identified patient writes or attaches a written complaint on the survey and requests resolution, the complaint must be treated as a grievance. If an identified patient writes or attaches a complaint to the survey, but does not request resolution, the ASC should treat this as a grievance if the ASC would usually treat such a complaint as a grievance.

Patient complaints that are considered grievances also include situations where a patient or a patient's representative or surrogate telephones the ASC with a complaint regarding the patient's care or with an allegation of abuse or neglect, or a failure of the ASC to comply with one or more of the CfCs.

Whenever the patient or the patient's representative or surrogate requests that his or her complaint be handled as a

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formal complaint or grievance, or when the patient requests a response from the ASC, the complaint is considered a grievance and all the grievance requirements apply.

Grievance Process

The ASC must have an established procedure in place for documenting the existence, submission, investigation, and disposition of a grievance.

As part of its obligation to notify patients of their rights, the ASC must inform the patient and/or the patient's representative or surrogate of the ASC's grievance process, including how to file a grievance.

All grievances submitted to any ASC staff member, whether verbally or in writing, must be reported by the staff to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to educate staff on their obligation to report all grievances, including whom they should report the grievance to.

All grievances must be investigated, but the regulation stresses this in particular for grievances related to treatment or care that the ASC provided or allegedly failed to provide. In its investigation the ASC should not only respond to the substance of the grievance, but should also use the grievance to determine if there are systemic problems indicated by the grievance that require resolution. An ASC would be well-advised to integrate its grievance process into its overall quality assessment and performance improvement program.

The ASC's grievance process must include a timeframe for the completion of the ASC's review of the grievance allegations, as well as for the ASC to provide a response to the person filing the grievance. The timeframe must be reasonable, i.e., allowing the ASC sufficient but not excessive time to conduct its review and issue its response. CMS does not mandate a particular timeframe. The application of the ASC's timeframe begins with the date of the receipt of the grievance by the ASC.

The ASC must document for each grievance how it was addressed. The ASC must also notify the patient or the patient's representative or surrogate, in writing, of the ASC's decision regarding each grievance.

The ASC may use additional methods to resolve a grievance, such as meeting with the patient's family. There are no restrictions on the ASC's use of additional effective methods to handle a patient's grievance. However, in all cases, the ASC must provide a written notice of its decision on each patient's grievance. The written notice must include the name of an ASC contact person, the steps the ASC took to investigate the grievance, the results of the grievance

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process, and the date the process was completed.

When a patient communicates a grievance to the ASC via email, the ASC may respond to the patient via email, pursuant to the ASC's policy. (Some ASC may have policies prohibiting communication to patients via email.) If the patient requests a response via email, the ASC may respond via email. If the email response contains the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the process was completed, the email meets the requirements for a written response.

In its written response to any grievance, the ASC is not required to include statements that could be used in a legal action against the ASC, but the ASC should provide adequate information to address the specific grievance. A form letter with generic statements about grievance process steps and results is not acceptable.

Survey Procedures:

o Determine whether the ASC has a written policy addressing the grievance process. Does the process specifically address how grievances are documented, how they are to be submitted, how they are to be investigated, and how the findings are to be used to dispose of the grievance? Does the policy comply with the regulatory requirements concerning reporting of grievances,, timeframe, and notice of disposition?

o Ask the ASC how many grievances it received during the past year. Ask how it documents the existence of grievances. Ask what the disposition was of grievances processed during that period. Ask to see a sample of grievance files. If this is a complaint survey concerning a grievance, ask to see grievances submitted at the time of the grievance that triggered the complaint survey.

o Review a sample of grievance files to determine if grievances are properly documented and handled in accordance with the ASC's policy and the regulatory requirements.

o Interview staff to see if staff is aware of the ASC's grievance policies. Do staff know the difference between a complaint handled on the spot and a grievance?

o Interview patients and/or representatives or surrogates to determine if they know how to file a grievance and who to contact if they have a complaint/grievance.

o Interview staff and patients to see how staff and patients are educated regarding to whom grievances and allegations should be reported.

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FED - Q0226 - GRIEVANCES - MISTREATMENT, ABUSE

Title GRIEVANCES - MISTREATMENT, ABUSE

Type Standard

CFR 416.50(d)(1), (2), & (3)

Regulation Definition

.... The following criteria must be met:

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

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

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

Interpretive Guideline

Grievances making allegations related to mistreatment; neglect; verbal, mental, sexual or physical abuse; or other serious allegations of harm must be fully documented. This means that all pertinent details of the allegation must be recorded and retained in the ASC's files. Documentation of the allegation should include, at a minimum, the date and time of the alleged occurrence, the location, the names of all individuals involved, and a description of the behavior that is alleged to have occurred within the ASC and to have constituted mistreatment, neglect or abuse or other serious harm.

The ASC regulation does define the terms "mistreatment," "neglect," or "abuse." However, the following definitions from long term care regulations may be helpful in making common sense judgments about whether an allegation fits into one of these categories:

o Neglect - Failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness (42 CFR 488.301).

o Abuse - The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish (42 CFR 488.301).

In addition, according to the Merriam Webster dictionary, "mistreatment" means to treat badly. It is also a synonym for abuse.

Finally, if there is applicable State law defining mistreatment, neglect or abuse in a healthcare facility, including ASCs, those definitions will apply.

All grievances alleging mistreatment, neglect or abuse that are submitted to any ASC staff member, whether verbally or in writing, must be reported immediately, i.e., as soon as possible, and at least on the same day, by the staff member to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to

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educate staff on their obligation to immediately report all grievances alleging mistreatment, neglect or abuse, including whom they should report the grievance to.

Grievances alleging mistreatment, neglect, abuse or other behavior that endangers a patient should be investigated as soon as possible, given the seriousness of the allegations and the potential for harm to patients. The ASC must conduct a careful investigation, balancing the need for speedy resolution with the need to ascertain all pertinent facts.

If the ASC confirms that the alleged mistreatment, abuse, neglect or other serious harm took place, then the ASC is obligated to report the event to the appropriate local or State authority, or even both. Depending on the specifics of the case and State or local law, the appropriate authority(ies) might include the local police, a State healthcare professional licensing board, a State agency that licenses the ASC, a State ombudsman, etc. The ASC should contact the appropriate authority promptly after it concludes its investigation of the grievance.

Survey Procedures:

- o Do the ASC's grievance policies and procedures separately address the process for investigating grievances alleging mistreatment, abuse, neglect or other serious harm? Do the policies and procedures conform to the regulatory requirement?
- o Interview staff to determine how they would handle a grievance alleging mistreatment, abuse, neglect or other serious harm? Do they know who to report the grievance to? Do they know that it should be reported immediately?
- o Ask the ASC who is the person authorized to handle such grievances. Interview that person to determine if he/she understands the requirements to fully document the allegation, conduct a prompt investigation, and to report substantiated grievances to the proper authority.
- o Ask the person authorized to handle such grievances if the ASC has had any grievances alleging mistreatment, neglect, abuse or other serious harm? If the answer is yes, ask to review the files for one or more such grievances. If such grievances were substantiated, verify whether there is documentation that the findings were reported to the appropriate authority.

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FED - Q0227 - RESPECT - PROPERTY & PERSON

Title RESPECT - PROPERTY & PERSON

Type Standard

CFR 416.50(e)(1)(i)

Regulation Definition

The patient has the right to the following:

- (i) Be free from any act of discrimination or reprisal.

Interpretive Guideline

The ASC may not take punitive action as a reprisal or discriminate against a patient. This includes reprisals or discrimination against a patient merely because he or she has exercised her rights. The ASC's patients' rights policies and procedures must indicate that the ASC does not engage in reprisals or discriminatory behavior.

Survey Procedures:

- o Interview staff to determine whether they are aware that the ASC may not discriminate against patients, or take punitive actions against any patient as a reprisal for some act on the patient's part.

- o Review the ASC's policies and procedures to determine whether it is clear that patients, or their representatives, or surrogates may exercise their rights without fear of reprisal.

- o Interview staff about how a patient who has filed a grievance or otherwise exercises his/her rights is treated. Is staff aware that they should not treat patients differently if the patient files a grievance?

FED - Q0228 - EXERCISE OF RIGHTS - GRIEVANCES

Title EXERCISE OF RIGHTS - GRIEVANCES

Type Standard

CFR 416.50(e)(1)(ii)

Regulation Definition

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

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

Interpretive Guideline

This requirement complements the requirement for the ASC to have a grievance system. Patients have the right to express a grievance regarding the treatment or care they receive in the ASC.

The patient, or the patient's representative or surrogate, as appropriate, may file a grievance, verbally or in writing,

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before the date of the scheduled procedure, on the date of the procedure, or after the date of the procedure. The regulation does not prescribe any limitation as to when a patient may submit a grievance. However, it is understood that, if a substantial amount of time has passed since the care episode addressed in the grievance, e.g., several years, that it may, depending on the nature of the grievance, be harder for the ASC to investigate the grievance and ascertain the pertinent facts.

Survey Procedures:

- o Interview ASC staff to determine if they are aware of the patient's right to file a grievance.

- o If the survey is related to a complaint alleging that an ASC ignored a patient's grievance, include that medical record in the sample and review it to determine if there is any evidence of a grievance as well as of action to respond to the grievance.

FED - Q0229 - EXERCISE OF RIGHTS - INFORMED CONSENT

Title EXERCISE OF RIGHTS - INFORMED CONSENT

Type Standard

CFR 416.50(e)(1)(iii)

Regulation Definition

[[(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 Guideline

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,

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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:

- o Who may obtain the patient's informed consent;
- o 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));
- o The content of the informed consent form and instructions for completing it;
- o The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- o Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and
- o 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

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requirements.

Example of a Well-Designed Informed Consent Process

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

- o A description of the proposed surgery, including the anesthesia to be used;
 - o The indications for the proposed surgery;
 - o 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;
 - o Treatment alternatives, including the attendant material risks and benefits;
 - o The probable consequences of declining recommended or alternative therapies;
 - o Who will conduct the surgical intervention and administer the anesthesia;
 - o 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;
 - o 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)
- o Determine whether the ASC has an informed consent policy that meets the regulatory requirements.

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- o 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?

- o 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.

- o 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.

- o 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.

FED - Q0230 - EXERCISE OF RIGHTS BY OTHERS

Title EXERCISE OF RIGHTS BY OTHERS

Type Standard

CFR 416.50(e)(2)& (3)

Regulation Definition

(2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

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

Interpretive Guideline

A patient who has been determined to be incompetent under a State legal process is not capable of exercising his or her rights independently. For such patients, the person appointed under State law to act on the patient's behalf may exercise any and all of the rights afforded to any ASC patient.

In addition, a competent patient may wish to delegate his/her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated, for example, if a complication requiring a treatment decision arises during a procedure. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate so that informed healthcare decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the ASC should provide that information to the patient.

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Survey Procedures

o Verify that there is a policy addressing the exercise of rights on behalf of a patient judged legally incompetent.

o Verify that there is a policy addressing the delegation by a patient of the exercise of rights to a representative.

FED - Q0231 - PRIVACY

Title PRIVACY

Type Standard

CFR 416.50(f)(1)

Regulation Definition

The patient has the right to -

(1) Personal privacy

Interpretive Guideline

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, dressing), during medical/surgical treatments, and when requested as appropriate.

People not involved in the care of the patient should not be present without the patient's consent while the patient is being examined or treated. Video or other electronic monitoring or recording methods should not be used when the patient is being examined without the patient's consent. If a patient requires assistance during toileting and other personal hygiene activities, staff should assist, giving the utmost attention to the patient's need for privacy. Privacy should also be afforded when staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending.

In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc. are not generally affected by this requirement.

Survey Procedures

Observe whether patients are provided privacy during examinations, activities concerning personal hygiene, and discussions regarding the patient's health status or healthcare, and any other appropriate situations.

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FED - Q0232 - SAFETY

Title SAFETY

Type Standard

CFR 416.50(f)(2)

Regulation Definition

[The patient has the right to -]

(2) Receive care in a safe setting

Interpretive Guideline

Each patient should receive care in an environment that a reasonable person would consider to be safe. The ASC staff should follow current standards of practice for patient environmental safety, infection control, and security. The ASC staff should also provide protection for the patient's emotional health and safety as well as the patient's physical safety. Respect, dignity, and comfort would be components of an emotionally safe environment.

Survey Procedures

o Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the ASC.

o Review safety, infection control and security documentation to determine if the ASC is identifying problems, evaluating those problems, and taking steps to ensure a safe patient environment.

o Observe the environment where care and treatment are provided.

o Review policy and procedures to see what steps the facility takes to curtail unwanted visitors and/or contaminated materials.

o Interview staff and patients to see if either have any concerns about the safety of the setting.

FED - Q0233 - SAFETY - ABUSE/HARASSMENT

Title SAFETY - ABUSE/HARASSMENT

Type Standard

CFR 416.50(f)(3)

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Regulation Definition

[The patient has the right to -]

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

Interpretive Guideline

An ASC must prohibit all forms of abuse, neglect (as a form of abuse), and harassment from staff, other patients, or visitors. The ASC must have mechanisms/methods in place ensure that patients are free from all forms of abuse, neglect, or harassment.

As discussed in the guidance for §416.50(d), abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish or mental illness and neglect is the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. The Merriam Webster Dictionary defines "harassment" as creating an unpleasant or hostile situation, especially by uninvited and unwelcome verbal or physical conduct.

The following components are suggested as necessary for effective protection from abuse, neglect or harassment:

Prevent. Persons with a record of abuse or neglect should not be hired or retained as employees. It is recommended that the ASC have a process in place to screen all applicants for employment or privileges to practice in the ASC.

Identify. The ASC should create and maintain a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.

Train. The ASC, during its orientation program, and through an on-going training program, should provide all employees with information regarding patient abuse and neglect, including who in the ASC is authorized to receive and handle allegations of abuse and neglect.

Investigate. The ASC ensures, in a timely and thorough manner, an objective investigation of all allegations of abuse, neglect, or mistreatment. This includes investigation not only of grievances from patients or their representatives, for which the grievance process prescribed in §416.50(d) must but used, but also allegations from any other source.

Respond. The ASC should assure that any and all incidents of abuse, neglect, or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with the applicable local, State, or Federal law.

Survey Procedures

Examine the extent to which the ASC has a system in place to protect patients from abuse, neglect, and harassment of all forms, whether from staff, other patients, visitors, or other persons. In particular, determine the extent to which the ASC addresses the following issues:

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- o Does the ASC have policies and procedures for investigating allegations of abuse and neglect in addition to the required grievance process that applies to allegations from patients or their representatives?
- o Does the ASC use the same process as for grievances alleging abuse and neglect? If not, what is the ASC's policy and process, including the process for training staff?
- o Interview staff to determine if staff members know what to do if they witness abuse and neglect.
- o Ask the ASC if it has had any allegations of patient abuse or neglect from any source during the past year? If it has, ask the ASC to provide the files and to describe how the matter was handled.
- o Review the records to see if the appropriate agencies were notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect?

FED - Q0234 - CONFIDENTIALITY OF CLINICAL RECORDS

Title CONFIDENTIALITY OF CLINICAL RECORDS

Type Standard

CFR 416.50(g)

Regulation Definition

The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

Interpretive Guideline

45 CFR Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security rules, establish standards for health care providers and suppliers that conduct covered electronic transactions, such as ASCs, among others, for the privacy of protected health information (phi), as well as for the security of electronic phi (ephi).

45 CFR 160.103 defines "Protected health information" as "individually identifiable health information" with specified exceptions and limitations.

45 CFR 160.103 defines "Individually identifiable health information" as "information that is a subset of health information, including demographic information collected from an individual, and:

- (1) Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision

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of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual;
and

- (i) That identifies the individual; or
- (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Privacy Rule

Individually identifiable health information that is held by HIPAA Covered Entities is protected under the Privacy Rule. Such information held by the "business associates" of Covered Entities is protected through contractual requirements in their contracts with the Covered Entities.

The Privacy Rule requires ASCs that are HIPAA Covered Entities to engage in activities such as:

- o Notifying patients about their privacy rights and how their information can be used.

- o Adopting and implementing privacy procedures for the ASC.

- o Training employees so that they understand the privacy procedures.

- o Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed within the ASC.

- o Securing patient records containing individually identifiable health information so that they are not readily available to those who do not need them.

To ease the burden of complying with these requirements, the Privacy Rule gives needed flexibility for ASCs to create their own privacy procedures, tailored to fit their size and needs. This scalability provides a more efficient and appropriate means of safeguarding protected health information than would any single standard. For example,

- o The privacy official at a small ASC may be the office manager, who will have other non-privacy related duties; the privacy official at a very large, high volume ASC may be a full-time position. The training requirement may be satisfied by a small ASC's providing each new member of the workforce with a copy of its privacy policies and documenting that new members have reviewed the policies; whereas a very large ASC may provide training through live instruction, video presentations, or interactive software programs.

- o The policies and procedures of small ASCs may be more limited under the Rule than those of a very large ASC,

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based on the volume of health information maintained and the number of interactions with those within and outside of the healthcare system.

The Department of Health and Human Services Office of Civil Rights, which is charged with responsibility for enforcing the Privacy Rule, provides more detailed information at the following website:
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>

A summary of the Privacy Rule's requirements may be found at:
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

Security Rule

The Department of Health and Human Services (HHS) also established standards, as required under HIPAA, for the security of health information. The Security Rule specifies a series of administrative, technical, and physical security standards with which covered entities must comply to ensure the confidentiality, integrity, and availability of all ePHI the covered entity creates, receives, maintains, or transmits. The standards include required and addressable implementation specifications. Unlike the Privacy Rule, which applies to protected health information in both electronic and non-electronic forms, the Security Rule only applies to PHI in electronic form. More information on the Security Rule may be found at the following Web site: <http://www.cms.hhs.gov/SecurityStandard/>.

Expectations for Surveyors

Surveyors are not expected to have detailed knowledge of the requirements of the Privacy and Security Rules, but instead are to focus on the steps the ASC takes to protect the confidentiality of clinical records, as well as to assure a patient's access to his/her own clinical record. If broader violations of the Privacy Rule are suspected, the case may be referred to the Regional Office, which may in turn forward the information to the Office of Civil Rights.

The ASC must have sufficient safeguards to ensure that access to all clinical records is limited to those individuals designated by law, regulation, and policy, or duly authorized by the patient to have access. No unauthorized access or dissemination of clinical records is permitted. Clinical records must be kept secure and only viewed when necessary by those persons participating in some aspect in the patient's care.

The right to the confidentiality of clinical records means safeguarding the content of information, including patient paper records, video, audio, and/or computer-stored information from unauthorized disclosure without the specific informed consent of the patient or patient's representative.

Confidentiality applies to both central storage of the closed clinical records and to open clinical records in use

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throughout the ASC.

Survey Procedures

o What policies and procedures does the ASC have in place to prevent the release or disclosure of individually identifiable patient information?

o Observe whether patient information is visible in areas where it can be viewed by visitors or other patients? How likely is it that an unauthorized individual could read and/or remove a patient's medical record?

o What security measures are in place to protect patient's medical records?

FED - Q0240 - INFECTION CONTROL

Title INFECTION CONTROL

Type Condition

CFR 416.51

Regulation Definition

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

Interpretive Guideline

This regulation requires the ASC to maintain an active program for the minimization of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another. (See NIAID website glossary)

The ASC's infection control program must:

- o Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases;
- o Be based on nationally recognized infection control guidelines;
- o Be directed by a designated health care professional with training in infection control;
- o Be integrated into the ASC's QAPI program;
- o Be ongoing;
- o Include actions to prevent, identify and manage infections and communicable diseases; and

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- o Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

The ambulatory care setting, such as an ASC, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time; surgical prep, recovery rooms and ORs are turned around quickly; patients with infections/communicable diseases may not be identified; and there is a risk of infection at the surgical site. Furthermore, due to the short period of time patients are in an ASC, the follow-up process to identify infections associated with the ASC requires gathering information after the patient's discharge rather than directly. It is essential that ASCs have a comprehensive and effective infection control program, because the consequences of poor infection control can be very serious. In recent years, for example, poor infection control practices related to injections of medications, saline or other infusates in some ASCs have resulted in the transmission of communicable diseases, such as hepatitis C, from one patient infected with the disease prior to his/her ASC visit to other ASC patients, and a requirement to notify thousands of other ASC patients of their potential exposure.

Survey Procedures

One surveyor is responsible for completion of the Infection Control Surveyor Worksheet, Exhibit 351, which is used to facilitate assessment of compliance with this Condition. However, each member of the survey team, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Infection Control regulatory requirements

FED - Q0241 - SANITARY ENVIRONMENT

Title SANITARY ENVIRONMENT

Type Standard

CFR 416.51(a)

Regulation Definition

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

Interpretive Guideline

The ASC must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases. All areas of the ASC must be clean and sanitary. This includes the waiting area(s), the pre-surgical prep area(s), the recovery room(s), and the operating or procedure rooms. The ASC must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and sanitary environment. Policies and procedures for a sanitary and functional environment should address the following:

- o Ventilation and water quality control issues, including measures taken to maintain a safe environment during

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internal or external construction/renovation;

- o Maintaining safe air handling systems in areas of special ventilation, such as operating rooms;
- o Techniques for food sanitation if employee food storage and eating areas are provided;
- o Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture;
- o Techniques for disposal of regulated and non-regulated waste; and
- o Techniques for pest control.

These activities must be conducted in accordance with professionally recognized standards of infection control practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

Survey Procedures §416.51(a)

Using the specific questions on the infection control survey worksheet related to environmental infection control to guide you:

- o Observe throughout the ASC the cleanliness of the waiting area(s), the recovery room(s), the OR/procedure rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, supply, storage areas, etc.
- o Interview staff to determine whether cleaning/disinfection takes place at the appropriate frequencies, using suitable EPA-registered agents. Ask for supporting documentation to confirm what staff say in interviews.
- o Determine whether the ASC has a procedure for decontamination after gross spills of blood or other bodily fluids.
- o Determine whether used sharps are disposed of properly.
- o Determine whether the ASC re-uses devices marketed for single use, and if so, does it send them to an FDA-approved vendor for reprocessing?

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FED - Q0242 - INFECTION CONTROL PROGRAM

Title INFECTION CONTROL PROGRAM

Type Standard

CFR 416.51(b)

Regulation Definition

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

Interpretive Guideline

The ASC must maintain an ongoing program to prevent, control, and investigate infections and communicable diseases. As part of this ongoing program, the ASC must have an active surveillance component that covers both ASC patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

The ongoing program must be based on nationally recognized infection control guidelines that the ASC has selected, after a deliberative process. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

The ASC should select one or more sets of guidelines that enable it to address the following key functions of an effective infection control program:

- o Maintenance of a sanitary ASC environment (see requirements of §416.51(a));
- o Development and implementation of infection control activities related to ASC personnel, which, for infection control purposes, includes all ASC medical staff, employees, and on-site contract workers (e.g., nursing staff employed by associated physician practice who also work in the ASC, housekeeping staff, etc);
- o Mitigation of risks associated healthcare-associated infections:
- o Identifying infections;
- o Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;

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- o Program evaluation and revision of the program, when indicated;

The following provides a more detailed overview of the types of activities related to these key functions.

- o ASC staff-related activities:

- Evaluating ASC staff immunization status for designated infectious diseases, for example, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);
- Policies articulating the authority and circumstances under which the ASC screens its staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority;
- Policies articulating when infected ASC staff are restricted from providing direct patient care or required to remain away from the facility entirely;
- New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases;
- Methods to evaluate staff exposed to patients with infections and communicable diseases;

- o Mitigation of risks contributing to healthcare-associated infections (HAI):

For the purposes of its surveillance activities in an acute care setting, the CDC defines an HAI as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the ASC.

HAIs may be caused by infectious agents from endogenous or exogenous sources. Endogenous sources are body sites, such as the skin, nose, mouth, gastrointestinal (GI) tract, or vagina that are normally inhabited by microorganisms. Exogenous sources are those external to the patient, such as patient care personnel, visitors, patient care equipment, medical devices, or the health care environment.

HAI risk mitigation measures include:

- o Surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as protocol to assure that antibiotic prophylaxis to prevent SSI for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery;
- Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate;

- o Other ASC healthcare-associated infection risk mitigation measures:

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- Promotion of hand hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;
- Measures specific to the prevention of infections caused by organisms that are antibiotic-resistant;
- Measures specific to safe practices for injecting medications and saline or other infusates;
- Requiring disinfectants and germicides to be used in accordance with the manufacturers' instructions;
- Appropriate use of facility and medical equipment, including air filtration equipment, UV lights, and other equipment used to control the spread of infectious agents;
- Educating patients, visitors, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the ASC and in the community.

o Identifying Infections

The ASC must conduct monitoring activities throughout the entire facility in order to identify infection risks or communicable disease problems. The ASC should document its monitoring/tracking activities, including the measures selected for monitoring, and collection and analysis methods. Activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN). Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether they have developed an infection associated with their stay in the ASC. See discussion of §416.44(a)(3).

The ASC must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

o Monitoring Compliance

It is not sufficient for the ASC to have detailed policies and procedures governing infection control; it must also take steps to determine whether the staff of the ASC adhere to these policies and procedures in practice. Are staff washing their hands prior to providing care to patients? Do personnel who prepare injections comply with all pertinent protocols? Is equipment properly sterilized or disinfected? Is the facility clean? The ASC must demonstrate that it has a process in place for regularly assessing infection control compliance.

o Program Evaluation

See the guidance for §416.51(b)(2), which requires that the infection control program must be an integral part of the ASC's quality assessment and performance improvement program.

An ASC presents different challenges for infection control as patients at varying levels of wellness are gathered in waiting or recovery areas, including the elderly, immuno-compromised patients, pre- and post-operative patients, and

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individuals with active or incubating infectious and communicable diseases. The length of stay for such individuals can range from brief to all day. Additionally, as ASCs are performing more invasive procedures, the level of risk for developing and transmitting infections and communicable diseases for patients and health care workers increases. The ASC should design its infection control program with these challenges in mind. For instance, the ASC should take appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. When such individuals are identified, the ASC could, for example, implement such prevention measures that would include prompt physical separation, implementation of respiratory hygiene/cough etiquette protocols, and appropriate isolation precautions based on the routes of transmission of the suspected infection.

Survey Procedures

o Use the infection control tool to assist in assessing compliance with this standard.

o Determine that there is an ongoing program for the prevention, control, and investigation of infections and communicable diseases among patients and ASC personnel, including contract workers and volunteers.

o Determine whether the policies and procedures of the program of the infection control program are implemented correctly. Specifically, surveyors should determine whether the ASC:

- Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand hygiene);
- Performs monitoring/tracking activities to identify infections; and
- Monitors compliance with all infection control program requirements.

o Review the parameters of the program to determine whether it is consistent with nationally recognized infection control guidelines. Is there documentation that the ASC has developed the procedures and policies of the program based on nationally recognized infection control guidelines?

FED - Q0243 - INFECTION CONTROL PROGRAM - DIRECTION

Title INFECTION CONTROL PROGRAM - DIRECTION

Type Standard

CFR 416.51(b)(1)

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Regulation Definition

The program is -
Under the direction of a designated and qualified professional who has training in infection control.

Interpretive Guideline

The ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program. The ASC must determine that the individual has had training in the principles and methods of infection control. Note that certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CIBC), while highly desirable, is not required, so long as there is documentation that the individual has training that qualifies the individual to lead an infection control program. The individual selected to lead the ASC's infection control program must maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

Although CMS does not specify the number of hours that the qualified individual must devote to the infection control program, resources must be adequate to accomplish the tasks required for the infection control program. The ASC should consider the type of surgical services offered at the facility as well as the patient population in determining the size and scope of the resources it commits to infection control. The CDC's HICPAC as well as professional infection control organizations, such as the APIC and the SHEA, publish studies and recommendations on resource allocation that ASCs may find useful.

Survey Procedures

- o Determine whether a qualified individual has been designated with the responsibility for leading the infection control program.

- o Review the personnel file of the infection control individual to determine whether he/she is qualified through ongoing education, training, or certification to oversee the infection control program.

FED - Q0244 - INFECTION CONTROL PROGRAM - QAPI

Title INFECTION CONTROL PROGRAM - QAPI

Type Standard

CFR 416.51(b)(2)

Regulation Definition

[The program is -]
An integral part of the ASC's quality assessment and performance improvement program

Interpretive Guideline

To reflect the importance of infection control the regulations specifically require that the ASC's infection control program must be integrated into its QAPI program. Among other things this means that infection control data and program activities are an ongoing component of the QAPI program, and that actions are taken in response to data

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analyses to improve the ASC's infection control performance. See the discussion related to §416.43, which articulates the ASC QAPI requirements.

Survey Procedures

o Determine whether the ASC's quality assessment and performance program includes measures/indicators and activities related to infection control on an ongoing basis.

o Determine whether there is evidence that the QAPI infection control activities result in specific actions designed to improve infection control within the ASC.

FED - Q0245 - INFECTION CONTROL PROGRAM

Title INFECTION CONTROL PROGRAM

Type Standard

CFR 416.51(b)(3)

Regulation Definition

The program is -

Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

Interpretive Guideline

The ASC's infection control professional must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the ASC. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the ASC's infection control outcomes. The plan should be specific to each particular area of the ASC, including, but not limited to, the waiting room(s), the recovery room(s), and the surgical areas. The designated infection control professional must assure that the program's plan of action addresses the activities discussed in the interpretive guidelines for §416.51(b), i.e.,

o Maintenance of a sanitary environment; (See discussion of §416.51(a))

o Development and implementation of infection control measures related to ASC personnel;

o Mitigation of risks associated with patient infections present upon admission;

o Mitigation of risks contributing to healthcare-associated infections;

o Active surveillance;

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- o Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements;
- o Plan evaluation and revision of the plan, when indicated;
- o Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable and infectious disease threats and outbreaks; and
- o Compliance with reportable disease requirements of the local health authority. (See discussion of §416.44(a)(3))

ASCs are required to have a process to follow up on each patient after discharge, in order to identify and track infections associated with the patient's stay in the ASC. An ASCs is not expected to establish routine post-surgical laboratory testing for infectious diseases, but if it learns of an infection in the post-discharge period from the patient or patient's physician, the ASC might consider inquiring whether there is a lab confirmation of an infectious disease, and, if there are indications that the infection was associated with the patient's stay in the ASC. If the ASC learns of a disease that is reportable under State law (including regulations), they must report it to the appropriate State authorities.

ASCs may delegate portions of this follow-up responsibility to the physicians on the ASC's staff who will see the patients in their office post-discharge only if the ASC's process includes a mechanism for ensuring that the results of the follow-up are reported back to the ASC and documented in the patient's medical record.

Survey Procedures

- o Ask the infection control professional to described actual examples of how, as a result of the action plan, infection control issues were identified and corrective or preventive actions were taken.
- o Ask for documentation of how those actions were evaluated to assure that they resulted in improvement.
- o Ask the infection control professional to review the ASC's infection control plan of action with you, explaining how it addresses the fundamental elements of an infection control program.
- o Does the plan address all the basic elements of infection control?
- o Ask the ASC's leadership how it tracks infections among patients and staff.
- o Ask for documentation of this tracking - is there tracking of all patients?

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o Ask the ASC's leadership what diseases are reportable to the State to verify the ASC's awareness of applicable reporting requirements.

o Ask the ASC if it has ever reported a reportable disease to the State. If yes, review the ASC's documentation of the case.

FED - Q0246 - COVID-19 Vaccination of Facility Staff

Title COVID-19 Vaccination of Facility Staff

Type Standard

CFR 416.51(c)(1)-(3)(i)-(x)

Regulation Definition

416.51 Condition for coverage-Infection control.

(c) Standard: COVID-19 vaccination of staff. The ASC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its patients:

- (i) Center employees;
- (ii) Licensed practitioners;
- (iii) Students, trainees, and volunteers; and
- (iv) Individuals who provide care, treatment, or other services for the center and/or its patients, under contract or by other arrangement.

Interpretive Guideline

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(2) The policies and procedures of this section do not apply to the following center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine, prior to staff providing any care, treatment, or other services for the center and/or its patients;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (c)(1) of this section;

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(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized or licensed COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID-19 vaccination requirements based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure

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documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

Effective 60 Days After Publication:

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

FED - Q0260 - PATIENT ADMISSION, ASSESSMENT AND DISCHARGE

Title PATIENT ADMISSION, ASSESSMENT AND DISCHARGE

Type Condition

CFR 416.52

Regulation Definition

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

Interpretive Guideline

The core objectives of this condition are to ensure that:

- o The patient can tolerate a surgical experience;
- o The patient's anesthesia risk and recovery are properly evaluated
- o The patient's post-operative recovery is adequately evaluated;
- o The patient received effective discharge planning; and
- o The patient is successfully discharged from the ASC

(See 72 FR 50477, August 31, 2007)

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All elements of the specific requirements of this condition concerning pre- and post-surgical assessments, together with the patient assessment requirements in the surgical services CfC at §416.42(a), must be met. Deficiencies related to §416.42(a), concerning the need for a physician to evaluate the patient for anesthesia risk and surgical procedure risk prior immediately before surgery, and for anesthesia recovery prior to discharge are to be considered when determining whether the requirements of this Condition have been met.

FED - Q0261 - PATIENT ASSESSMENT AND ADMISSION

Title PATIENT ASSESSMENT AND ADMISSION

Type Standard

CFR 416.52(a)(1)

Regulation Definition

Standard: Patient assessment and admission.

- (1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must--
- (i) Include the timeframe for medical history and physical examination to be completed prior to surgery.
 - (ii) Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.
 - (iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

Interpretive Guideline

Guidance pending and will be updated in future release.

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FED - Q0262 - ADMISSION AND PRE-SURGICAL ASSESSMENT

Title ADMISSION AND PRE-SURGICAL ASSESSMENT

Type Standard

CFR 416.52(a)(2)-(3)

Regulation Definition

Standard: Admission and Pre-surgical Assessment

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

Interpretive Guideline

Guidance pending and will be updated in future release.

FED - Q0263 - ADMISSION ASSESSMENT - RECORD

Title ADMISSION ASSESSMENT - RECORD

Type Standard

CFR 416.52(a)(4)

Regulation Definition

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

Interpretive Guideline

Guidance pending and will be updated in future release.

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FED - Q0264 - POST-SURGICAL ASSESSMENT

Title POST-SURGICAL ASSESSMENT

Type Standard

CFR 416.52(b)

Regulation Definition

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

Interpretive Guideline

Each patient must be assessed after the surgery is completed. In accordance with the requirements of §416.42(a)(2), a physician or anesthesiologist must assess each patient for recovery from anesthesia after the surgery. See the interpretive guidelines for §416.42(a)(2) for a discussion of the requirements for a post-anesthesia assessment.

In addition, each post-surgical patient's overall condition must be assessed and documented in the medical record, in order to determine how the patient's recovery is proceeding, what needs to be done to facilitate the patient's recovery, and whether the patient is ready for discharge or in need of further treatment or monitoring.

Except for the assessment of the patient's recovery from anesthesia, the assessment may be performed by a physician, another qualified practitioner, or a registered nurse with post-operative care experience who is permitted, under applicable State laws as well as general standards of practice and the ASC's clinical policy, to assess patients' post-operatively.

If the assessment identifies post-surgical patient needs that must be addressed in order for the patient to be safely discharged, or, in the case of patients who develop needs that exceed the capabilities of the ASC appropriately and timely transferred to a hospital for further care, the ASC must address those patient needs. This must be documented in the discharge notes in the patient's medical record.

Survey Procedures

o Verify through observation of post-surgical patient care and through record review whether the ASC evaluates each patient after surgery, both for recovery from anesthesia, as required under §416.42(a)(2), and for his/her overall recovery from the surgery and suitability for discharge.

o Are the post-surgical assessments performed by qualified personnel, i.e., a physician or anesthesiologist assesses the recovery from anesthesia, while the overall assessment is performed by a physician, other licensed practitioner or RN with appropriate experience in post-operative care? Where an RN performs an assessment, is there documentation of the RN's qualifications to do so?

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o Does the ASC identify patient needs related to safe discharge, or, as applicable, does it identify patients who require transfer to a hospital for further treatment that exceeds the ASC's capabilities? Do the records reflect actions by the ASC to address the needs it has identified?

o Do the medical records reflect the post-surgical assessment, needs identified, and actions taken by the ASC to address those needs in the medical record's discharge notes?

FED - Q0265 - DISCHARGE - SUPPLIES AND INFORMATION

Title DISCHARGE - SUPPLIES AND INFORMATION

Type Standard

CFR 416.52(c)(1)

Regulation Definition

The ASC must -

Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

Interpretive Guideline

Each patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions.

Either before the surgery or before discharge each patient must be provided with:

- o Prescriptions they will need to fill associated with their recovery from surgery;
- o Written instructions that specify actions the individual should take in the immediate post-operative, post-discharge period to promote their recovery from the surgery; warning signs of complications to be alert for, etc.
- o How to contact the physician who will provide follow-up care to the patient. When appropriate, the ASC must make an appointment with the physician for follow-up care.

The ASC must also provide supplies, such as gauze, bandages, etc., sufficient for the patient's needs through the first night after the surgery.

Survey Procedures

- o Determine whether there is a copy of the discharge instructions provided to the patient in the patient's medical record.

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- o Look at the discharge instructions in the sample of records under review, as well as for patients being discharged while the ASC is being surveyed. Do the discharge instructions include post-operative care instructions for the patient? Do they indicate if the patient was provided prescriptions, if applicable? Do they provide physician contact information?

- o Ask the ASC when and how it schedules follow-up appointments with the physician for patients.

- o Ask the ASC what types of supplies it typically provides to patients upon discharge. Observe whether patients being discharged during the survey are provided any supplies to cover their overnight needs.

FED - Q0266 - DISCHARGE - ORDER

Title DISCHARGE - ORDER

Type Standard

CFR 416.52(c)(2)

Regulation Definition

[The ASC must -]

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 Guideline

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)

- o Determine whether there is a discharge order, signed by the physician who performed the surgery/procedure, in the sample of medical records being reviewed.

- o Determine whether there is a discharge order signed by the physician for patients being discharged while the

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survey takes place.

FED - Q0267 - DISCHARGE WITH RESPONSIBLE ADULT

Title DISCHARGE WITH RESPONSIBLE ADULT

Type Standard

CFR 416.52(c)(3)

Regulation Definition

[The ASC must -]

Ensure all patients are discharged in the company of a responsible adult except those patients exempted by the attending physician.

Interpretive Guideline

Unless the physician who is responsible for the patient's care in the ASC has exempted the patient, the ASC may not discharge any patient who is not accompanied by a responsible adult who will go with the patient after discharge. ASCs would be well-advised to develop policies that address what criteria a physician should consider when deciding a patient does not need to be discharged in the company of a responsible adult. Exemptions must be specific to individual patients, not blanket exemptions to a whole class of patients.

Survey Procedures

Do the medical records being reviewed identify for each patient the responsible adult who will accompany the patient after discharge, or, alternatively, a specific exemption for this patient from this requirement by the physician?

FED - Q9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline