



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-20-Acute Care

DATE: March 15, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidance for Hospitals, Critical Access Hospitals (CAHs) and Ambulatory Surgical Centers (ASCs) Related to Various Rules Reducing Provider/Supplier Burden

Memorandum Summary

- ***Various Burden Reduction Regulations Adopted:***
 - On October 24, 2011, the Centers for Medicare & Medicaid Services (CMS) published a final rule revising the ASC Patient Rights regulation at 42 CFR 416.50, effective December 23, 2011 (76 FR 65886).
 - On November 30, 2011, CMS published the Hospital Outpatient Prospective Payment System rule, effective January 1, 2012 (76 FR 74122). The rule included revisions to 42 CFR 489.20(w), governing required notice to patients by hospitals and CAHs that do not have an doctor of medicine (MD) or doctor of osteopathy (DO) present in the hospital or CAH at all times.
 - On May 16, 2012, CMS published two final rules (77 FR 29002 & 77 FR 29034) which included provisions:
 - *For Hospitals:* Revisions of the Conditions of Participation (CoPs) concerning governing body, patient's rights, medical staff, nursing services, medical records, pharmaceutical services, infection control, outpatient services and transplant center organ recovery and receipt.
 - *For CAHs:* Revisions of the CoPs concerning definitions, personnel qualifications, physical plant and environment, and surgical services.
 - *For ASCs:* Revision of the Condition for Coverage (CfC) for environment.
- ***State Operations Manual (SOM) Revisions:*** Appendices A (hospitals), W (CAHs) and L (ASCs) are revised to reflect these final rules, except that transplant center guidance will be updated separately. In addition, we are taking this opportunity to make minor technical corrections to Appendix L.
- ***Automated Survey Processing Environment (ASPEN) Changes:*** ASPEN regulatory text and tags have been updated for hospitals and CAHs. ASC updates will be made in ASPEN at a later date. Some tags have been renumbered, consolidated or deleted. A crosswalk from the old to the new tags is provided.

Hospital/CAH Required Notices

The Hospital Outpatient Prospective Payment System rule published on November 30, 2011 (76 FR 74122) and effective January 1, 2012 included revisions to 42 CFR 489.20(w), governing required notice to patients by hospitals and CAHs that do not have an MD or DO present in the hospital or CAH at all times (i.e., 24 hours per day, 7 days per week).

Key Changes:

- ***Outpatient services:*** Notice is only required for those outpatients receiving observation services, surgery, or any other procedure using anesthesia. Previously, notice was required to be given to all outpatients. In the preamble to the revised rule, CMS stated that providing notice to all outpatients was not necessary for patient safety and was too burdensome for hospitals and CAHs. The revised rule instead limits outpatient disclosures to those patients receiving observation services or procedures using anesthesia, since these are situations where the risk of an emergency is greater, or the length of the outpatient visit makes them more like hospital inpatient situations. Notice continues to be required for all hospital and CAH inpatients.
- ***ED signage instead of individual notice:*** In the emergency department, signage regarding this notice is required to be posted publicly; individual notices to each patient are not required, unless the patient is admitted as an inpatient or provided observation services.
- ***Multi-campus hospitals:*** In the case of multi-campus hospitals, a separate determination is required for each campus (including main location, remote location, or satellite location) providing inpatient services whether an MD or DO is present in each location at all times, and thus whether or not a notice is required for that campus.

Clarifications Added to Guidance:

- ***Timing of notice in an emergency:*** The requirement for the hospital or CAH to get a signed acknowledgement of the disclosure from the patient before admitting the patient or providing applicable outpatient services, but qualifies this in the case of an emergency when it is in the best interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances, the hospital must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.
- ***Off-campus same-day surgery:*** For an off-campus provider-based hospital or CAH same-day surgery department, notice to patients is only required if the main provider campus does not have an MD or DO present 24/7.

Physician-Owned Hospitals: There is an additional disclosure requirement at §411.362(b)(5)(i) that applies only to physician-owned hospitals. Section 411.362(b)(5)(i) implements provisions of Section 6001(a) of the Affordable Care Act and provides that physician-owned hospitals must continue to provide notice to all inpatients and all outpatients when they do not have an MD/DO on-site 24/7. However, this regulation is **not** enforced through the survey and certification

process, and there is no need for State Survey Agencies (SAs) to apply a different standard to physician-owned hospitals and CAHs when assessing compliance under the CoPs. In other words, §489.20(w) applies to all hospitals and CAHs, including those that are physician-owned.

Hospital CoP Changes:

Governing Body:

- **Multi-hospital governing body:** Under §482.12, if a hospital is part of a hospital system of separately certified hospitals, the system has the option of having a single governing body serve as the governing body for each hospital within that system. Each separately certified hospital must continue to demonstrate its compliance with the Medicare CoPs on a hospital-specific basis.
- **Medical staff membership on the governing body:** The regulation also included a new requirement for a member of the medical staff to serve on the governing body. However, consistent with SC-12-36 HOSPITAL, issued June 15, 2012, we are not providing guidance on this provision at this time. Subsequent to adoption of this regulation, numerous questions and concerns were raised by various stakeholders that affect survey and certification assessment of compliance with this requirement, including the questions about interaction of this requirement with other Federal, State or local laws. In addition, a recent notice of proposed rulemaking published on February 7, 2013 (78 FR 9216) proposes to amend this requirement. Therefore, surveyors should not interpret on their own the requirement concerning medical staff membership on the governing body, and must not issue citations related to this specific provision.

In addition, we instructed the three accreditation organizations with a CMS-approved Medicare hospital accreditation program, the American Osteopathic Association (AOA), Det Norske Veritas (DNV) Healthcare, and The Joint Commission, not to revise their accreditation standards related to this aspect of the composition of the governing body until we have addressed the issue completely.

Patients Rights Restraint/Seclusion Death Reporting:

- **Soft wrist restraints only:** Hospitals must maintain an internal log of all deaths associated with the use of restraints where the only restraints used were two-point soft wrist restraints. There is no longer a need for them to submit reports of these cases directly to the RO.
- **All other cases:** All other deaths associated with use of restraint or seclusion must be reported to the CMS Regional Office no later than close of business on the next business day following knowledge of the patient's death. Reporting may be by telephone, facsimile or electronically, as determined by CMS. CMS has created a new worksheet, included in the attachment as a draft Exhibit to be used by hospitals for facsimile or electronic submission.

Medical Staff

- **Non-physician members:** The revised regulation clarifies that hospitals have the flexibility, consistent with state scope of practice laws, to include non-physician practitioners on the

medical staff in addition to physician practitioners. According to the final rule preamble, all practitioners granted privileges must be members of the medical staff. Since adoption of the final rule concerns were raised by various stakeholders that the revised regulation may conflict with state law requirements that limit medical staff membership to physicians. We are further exploring this issue and will issue revised guidance at a later time. Therefore, surveyors should not interpret on their own the requirement concerning medical staff membership versus privileges.

In addition, we are instructing the three accreditation organizations with a CMS-approved Medicare hospital accreditation program, the American Osteopathic Association (AOA), Det Norske Veritas (DNV) Healthcare, and The Joint Commission, that they are not required to include this provision in their accreditation standards at this time.

- **Medical staff leadership:** As permitted under state law, hospitals have the flexibility to assign a doctor of podiatric medicine to be responsible for the organization and conduct of the medical staff.

Nursing Services

- **Interdisciplinary care plan:** Hospitals have the flexibility to incorporate the nursing care plan required for each inpatient into an interdisciplinary care plan.
- **Standing orders:** Drugs and biologicals may be prepared and administered on the orders contained in pre-printed and electronic standing orders, order sets and protocols (collectively referred to as “standing orders” in our guidance) only if the standing orders meet the requirements of the medical records CoP.
- **Blood transfusion training:** The requirement that personnel who administer blood transfusions, other than doctors of medicine or osteopathy, have special training has been eliminated.
- **Self-administered medications/Medications brought from home:** Hospitals have a new option to permit self-administration by patients (or the patient’s caregiver/support person) of hospital-issued medications and/or medications brought by the patient from home.

Medical Records

- **Authentication of orders:** All orders, including verbal orders, must be dated, timed and promptly authenticated by the ordering practitioner or another practitioner responsible for the care of the patient, in accordance with state law, including scope of practice laws, hospital policy and medical staff bylaws, rules and regulations.

A specific timeframe for authentication of verbal orders has been eliminated.

- **Standing orders criteria:** Standing orders may be used only if the hospital: ensures the orders are reviewed and approved by the medical staff and the hospital nursing and pharmacy leadership; demonstrates the orders are consistent with nationally recognized and evidence-

based guidelines; ensures periodic review to determine their continuing usefulness and safety; and ensures that the orders are dated, timed and authenticated promptly.

Pharmaceutical Services

- **Internal reporting:** The provision concerning internal reporting of drug administration errors, adverse drug reactions and incompatibilities has been revised to correct the name of the program receiving such reports to “quality assessment and performance improvement program.” Thus, not only must these reports be made to the attending physician, but also, if appropriate, to the hospital’s quality assessment and performance improvement program.

Infection Control

- **Incident log:** The requirement to maintain a log of incidents of infection and communicable diseases has been eliminated. Hospitals are still expected to conduct appropriate surveillance activities, consistent with nationally recognized infection control standards of practice.

Outpatient Services

- **Direction of outpatient services:** Hospitals no longer are required to have a single individual directing all outpatient services, providing more flexibility for hospitals to organize their management of these services in the manner they find most efficient and effective, so long as one or more individuals is assigned responsibility for each outpatient service.
- **Outpatient staffing:** Hospitals must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Transplant Services

- Transplant center guidance is handled separately.

CAH CoP Changes:

Personnel Qualifications:

- The qualifications to be considered a clinical nurse specialist have been updated to be consistent with the statutory definition.

Definition & Physical Plant and Environment; Provision of Services

- The definition of “direct services,” i.e., services provided by employees of the CAH, has been removed.
- All references to the CAH providing certain services “directly” have been removed. CAHs now have the flexibility to provide required services either directly, i.e., through staff

employed by the CAH, or under arrangement. However, regardless of whether the services are provided directly or under arrangement, the minimum required services listed under §485.635(b) must be available on-site at the CAH.

Surgical Services

- The regulatory text has been clarified to state explicitly that surgical services are optional services for a CAH.

ASC CfC Changes:

Environment

- An older standard that was duplicative of portions of the infection control CfC that became effective in 2009 has been eliminated.
- The regulation no longer prescribes a specific list of emergency equipment that must be available in every ASC operating room. Instead, the ASC's governing body and medical staff are required to specify the types of emergency equipment required that is appropriate to the ASC's patient population, to make it available immediately during emergencies, and to ensure it is maintained by appropriate personnel.

Patients' Rights – Required Notices

- An ASC:
 - Is no longer required to provide notice of patient rights in advance of the date of the procedure. Provision of both verbal and written notice on the same day as, but prior to the start of, the surgical procedure is acceptable.
 - Must provide notice of patient rights to the patient, the patient's representative, or the patient's surrogate. The prior rule made no mention of a surrogate.
 - Must disclose physician financial interest or ownership in the ASC in accordance with 42 CFR Part 420 and, where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. The prior rule required this disclosure be made in advance of the date of the procedure, however, the revisions to the rule deleted this requirement. The disclosure must be in writing.

ASC Infection Control Surveyor Worksheet

We are taking this opportunity to update Exhibit 351, the ASC Infection Control Surveyor Worksheet, to improve its clarity. Changes are not substantive. As a reminder, surveyors must assess all items on the worksheet whenever conducting a full survey or a complaint survey involving the infection control CfC. For FY 2013 representative sample ASC validation surveys and surveys of ASCs included in the mandatory, randomly selected sample of ASCs which must be surveyed this fiscal year, SAs must also submit a copy of the completed worksheet to CMS's contractor, Acumen. No other completed ASC worksheets should be submitted to Acumen.

CMS is working with Acumen to create a fillable PDF version of the ASC Infection Control Surveyor Worksheet, similar to that used in the Hospital Patient Safety Initiative Pilot. This will facilitate submission by the SAs to Acumen of completed worksheets for the ASCs assigned in FY 2013 for either representative sample validation or non-deemed random sample surveys. The fillable PDF version and instructions for submission will be provided to SAs in the near future. In the meantime, it is acceptable to submit to Acumen faxed or electronic copies of the:

- existing Exhibit 351, for surveys completed prior to release of this memorandum; and
- attached revised Exhibit 351. for surveys completed after the date of this memorandum but prior to distribution of the fillable PDF version of the worksheet.

ASPEN Changes

Changes have already been implemented in ASPEN to reflect revised regulatory text for hospitals and CAHs, and will be implemented at a future date for ASCs. In some cases, tags have been renumbered, deleted, or consolidated. A crosswalk from the old to the new tags is attached.

Advance copy of the updated SOM

An advance copy of the updated portions of the SOM is attached and may differ slightly from the final version, which will be released at a later date.

Questions about this guidance should be addressed to: the Survey & Certification Division of Acute Care Services e-mail mailbox at hospitalscgs@cms.hhs.gov

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachments: (3)

Crosswalk from old to new ASPEN Tags

Advance copy of updated SOM

Updated Infection Control Surveyor Worksheet

cc: Survey and Certification Regional Office Management

Crosswalk from Old to New Tags for ASPEN Patches and Conversion

Old Tag	New Tag
Hospitals	
A-0043	A-0043 §482.12 Condition of Participation: Governing Body <i>There must be</i> an effective governing body <i>that is</i> legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body...
A-0214	A-0213 §482.13(g) Standard: Death Reporting Requirements: - Hospitals must report deaths associated with the use of seclusion or restraint. <i>(1) With the exception of deaths described under paragraph (g)(2) of this section, the</i> hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death: (i) Each death that occurs while a patient is in restraint or seclusion. (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. <i>(3) The staff must document in the patient's medical record the date and time the death was:</i> <i>(i) Reported to CMS for deaths described in paragraph(g)(1) of this section....</i>

Old Tag	New Tag
New content for this Tag	A-0214 <i>§482.13(g) Standard: Death Reporting Requirements: [- Hospitals must report deaths associated with the use of seclusion or restraint.]</i> <i>(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient’s wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal or other system, the following information:</i> <i>(i) Any death that occurs while a patient is in such restraints.</i> <i>(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.</i> <i>(3) The staff must document in the patient’s medical record the date and time the death was:</i> <i>...(ii)Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.</i> <i>(4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows:</i> <i>(i) Each entry must be made not later than seven days after the date of death of the patient;</i> <i>(ii) Each entry must document the patient’s name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es).</i> <i>(iii) The information must be made available in either written or electronic form to CMS immediately upon request.</i>
A-0339	A-0339 §482.22(a) Standard: <i>Eligibility and process for appointment to</i> medical staff. The medical staff must <i>include</i> doctors of medicine or osteopathy. <i>In</i> accordance with State law, <i>including scope of practice laws, the medical staff</i> may also <i>include</i> other <i>categories of non-physician</i> practitioners <i>determined as eligible for appointment</i> by the governing body.
A-0341	A-0341 §482.22(a)(2) - The medical staff must examine <i>the</i> credentials of <i>all eligible</i> candidates for medical staff

Old Tag	New Tag
	membership and make recommendations to the governing body on the appointment of <i>these</i> candidates, <i>in accordance with State law, including scope of practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules and regulations, in addition to the requirements contained in this section.</i>
A-0347	A-0347 §482.22(b) Standard: Medical Staff Organization and Accountability The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only <i>to one of the following:</i> (i) an individual doctor of medicine or osteopathy., (ii) a doctor of dental surgery or dental medicine, <i>when permitted by State law of the State in which the hospital is located.,</i> (iii) <i>A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.</i>
A--0396	A-0396 §482.23(b)(4) - The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. <i>The nursing care plan may be part of an interdisciplinary care plan.</i>

Old Tag	New Tag
A -0404 – combine with A-0405 §482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3). A -0405 (1) - All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.	A-0405 §482.23(c) Standard: Preparation and administration of drugs. <i>(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.</i> <i>(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i> §482.23(c)(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
A-0406	A-0406 <i>§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</i> §482.23(c)(3)- With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy and who is responsible for the care of the patient as specified under §482.12(c). <i>§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>

Old Tag	New Tag
A-0407	A-0407 §482.23(c)(-3)(i) If verbal orders are used, they are to be used infrequently.
A-0408	A-0408 §482.23(c)(3)(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.
A-0409	A-0409 §482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
A-0410	A-0410 §482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.
New Tag	A-0412 <i>§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.</i> <i>(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:</i> <i>(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.</i> <i>(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).</i> <i>(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).</i> <i>(D) Address the security of the medication(s) for each patient.</i> <i>(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate) in the patient's medical record.</i>

Old Tag	New Tag
New Tag	A-0413 <i>[§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.]</i> <i>§482.23(c)(6)(ii)</i> <i>If the hospital allows for a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:</i> <i>(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medication the patient brought into the hospital.</i> <i>(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).</i> <i>(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity;</i> <i>(D) Address the security of the medication(s) for each patient.</i> <i>(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.</i>
A-0454	A-0454 §482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner <i>or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>

Old Tag	New Tag
New content for this Tag number. Previous citations under old Tag A 0457 will be attributed to Tag A-0454	A-0457 <i>§482.24(c)(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:</i> <i>(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;</i> <i>(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;</i> <i>(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and</i> <i>(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>
A-0458	A-0458 §482.24(c)(4) - All records must document the following, as appropriate: (i) Evidence of-- (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
A-0461	A-0461 §482.24(c)(4) - [All records must document the following, as appropriate: (i) Evidence of --] (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
A-0463	A-0463 §482.24(c)(4) [All records must document the following, as appropriate:] (ii) - Admitting diagnosis.

Old Tag	New Tag
A-0464	A-0464 §482.24(c)(4) [All records must document the following, as appropriate:] (iii) - Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.
A-0465	A-0465 §482.24(c)(4) [All records must document the following, as appropriate:] (iv) - Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.
A-0466	A-0466 §482.24(c)(4) [All records must document the following, as appropriate:] - Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.
A-0467	A-0467 §482.24(c)(4) [All records must document the following, as appropriate:] (vi) - All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
A-0468	A-0468 §482.24(c)(4) [All records must document the following, as appropriate:] (vii) - Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.
A-0469	A-0469 §482.24(c)(4) [All records must document the following, as appropriate:] (viii) - Final diagnosis with completion of medical records within 30 days following discharge.

Old Tag	New Tag
A-0508	A-0508 §482.25(b)(6) - Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's <i>quality assessment and performance improvement program</i> .
A-0748	A-0748 §482.42(a) Standard: Organization and Policies A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases....
A-0749	A-0749 §482.42(a)–...The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
A-0750 is deleted	
A-0756	A-0756 §482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services The chief executive officer, the medical staff, and the director of nursing must-- (1) Ensure that the hospital-wide quality <i>assessment and performance improvement (QAPI)</i> program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas.
A-1079	A-1079 §482.54(b) Standard: Personnel The hospital must -- (1) Assign <i>one or more</i> individuals to be responsible for outpatient services. (2) Have appropriate professional and nonprofessional personnel available <i>at each location where outpatient services are offered, based on the scope and complexity of outpatient services.</i>

Old Tag	New Tag
CAHs	
C-0221	C-0221 §485.623(a) Standard: Construction The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.
C-0273	C-0273 §485.635(a)(3) The policies include the following: (i) A description of the services the CAH furnishes, <i>including</i> those furnished through agreement or arrangement.
C-0281	C-0281 §485.635(b) Standard: <i>Patient</i> Services (1) General. The CAH <i>provides</i> those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity <i>hospital</i> outpatient department or emergency department. These <i>CAH</i> services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.
C-0282	C-0282 §485.635(b)(2) Laboratory Services The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include: (i) Chemical examination of urine by stick or tablet method or both (including urine ketones). (ii) Hemoglobin or hematocrit. (iii) Blood glucose. (iv) Examination of stool specimens for occult blood. (v) Pregnancy tests; and (vi) Primary culturing for transmission to a certified laboratory

Old Tag	New Tag
C-0283	C-0283 §485.635(b)(3) Radiology services. Radiology services furnished at the CAH are provided by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.
C-0284	C-0284 §485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical <i>services</i> as a first response to common life-threatening injuries and acute illness.

Old Tag	New Tag
C-0320	C-0320 §485.639 Condition of Participation: Surgical Services. <i>If a CAH provides surgical services, surgical</i> procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.
ASCs	
Tag Q-0103 is deleted. Former citations should be tracked to Q-0242	
Q-0105	Q-0105 §416.44(c) Standard: Emergency Equipment <i>The ASC medical staff 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:</i> <i>(1) Be immediately available for use during emergency situations.</i> <i>(2) Be appropriate for the facility's patient population.</i> <i>(3) Be maintained by appropriate personnel.</i>
New Tag – citations previously under Q-0220 should be tracked to this tag	Q-0219 §416.50 Condition for Coverage - Patient Rights The ASC must inform the patient or the patient's representative <i>or surrogate</i> of the patient's rights, and must protect and promote the exercise of <i>these</i> rights, <i>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.</i>
New content for old Tag Q-0219 this is the tag for issuing a standard-level citation	Q-0220 <i>§416.50.... 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.</i>

Old Tag	New Tag
Q-0221	Q-0221 §416.50(a) Standard: Notice of Rights <i>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.</i>
Q-0223	Q-0223 §416.50(b) Standard: Disclosure of physician financial interest or ownership The ASC must also disclose, <i>in accordance</i> with the intent of 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.
Q-0224	Q-0224 §416.50(c) Standard: Advance Directives The ASC must comply with the following requirements: (1) Provide the patient or, as appropriate, the patient’s representative with <i>written</i> information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms. (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.

Old Tag	New Tag
Q-0225	Q-0225 §416.50(d) Standard: Submission and investigation of grievances 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. <i>The following criteria must be met:</i> ... (4) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (5) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient’s representative, <i>or the patient’s surrogate</i> regarding treatment or care that is (or fails to be) furnished. (6) The ASC must document how the grievance was addressed, as well as provide the patient, <i>the patient’s representative, or the patient’s surrogate</i> with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.
Q-0226	Q-0226 §416.50(d) Standard: Submission and investigation of grievances.... <i>The following criteria must be met:</i> (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. (3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

Old Tag	New Tag
Q-0227	Q-0227 §416.50(e) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to <i>the following</i>: (i) Be free from any act of discrimination or reprisal.
Q-0228	Q-0228 §416.50(e) Standard: Exercise of rights and respect for property and person. [<i>(1)</i> The patient has the right <i>to the following</i>:] (ii) Voice grievances regarding treatment or care that is (or fails to be) provided.
Q-0229	Q-0229 §416.50(e) Standard: Exercise of rights and respect for property and person. [<i>(1)</i> 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.
Q-0230	Q-0230 §416.50(e) Standard: Exercise of rights and respect for property and person. (2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

Old Tag	New Tag
Q-0231	Q-0231 §416.50(f) Standard: Privacy and Safety. The patient has the right to – (1) Personal privacy.
Q-0232	Q-0232 §416.50(f) Standard: Privacy and Safety. The patient has the right to – (2) Receive care in a safe setting.
Q-0233	Q-0233 §416.50(f) Standard: Privacy and Safety. The patient has the right to – (3) Be free from all forms of abuse or harassment.
Q-0234	Q-0234 §416.50(g) Standard: Confidentiality of Clinical Records The ASC must comply with the Department’s rules for the privacy and security of individually identifiable health information, as specified at 45 CFR Parts 160 and 164.

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date:

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix W, Interpretive Guidelines for Critical Access Hospitals, and Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers

I. SUMMARY OF CHANGES: Changes are made to reflect revised regulations adopted for hospitals in 42 CFR Part 482, critical access hospitals in 42 CFR Part 485, Subpart F, and ambulatory surgical centers in 42 CFR Part 416.

NEW/REVISED MATERIAL - **EFFECTIVE DATE*:** Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A Table of Contents
R	Appendix A/§482.12 Condition: Governing Body
R	Appendix A/§482.13(b) Standard: Patient Rights
R	Appendix A/§482.13(g) Standard: Patient Rights
R	Appendix A/§482.22(a) Standard: Medical Staff
R	Appendix A/§482.22(b) Standard: Medical Staff
R	Appendix A/§482.23(b) Standard: Nursing Services
R	Appendix A/§482.23(c) Standard: Nursing Services
R	Appendix A/§482.24(c) Standard: Medical Record Services
R	Appendix A/§482.25(b) Standard: Pharmaceutical Services
R	Appendix A/§482.42(a) Standard: Infection Control
R	Appendix A/§482.42(b) Standard: Infection Control
R	Appendix A/§482.54(b) Standard: Outpatient Services
R	Appendix W Table of Contents
R	Appendix W/§485.608(a) Standard: Compliance with Federal, State, And Local Laws and Regulations
R	Appendix W/§485.610 Condition: Status and Location

R	Appendix W/§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification
R	Appendix W/§485.623(a) Standard: Physical Plant and Environment
R	Appendix W/§485.635(b) Standard: Provision of Services
R	Appendix W/§485.639 Condition: Surgical Services
R	Appendix L Table of Contents
R	Appendix L ASC Survey Protocol
R	Appendix L/§416.2 Definitions
R	Appendix L/§416.43 Condition: Quality Assessment and Performance Improvement
D	Appendix L/§416.44(a)(3) Standard: Environment
R	Appendix L/§416.44(b) Standard: Environment
R	Appendix L/§416.44(c) Standard: Environment
R	Appendix L/§416.45 Standard: Medical Staff
R	Appendix L/§416.47 Standard: Medical Records
R	Appendix L/§416.47(b) Standard: Medical Records
R	Appendix L/§416.50 Standard: Patient Rights
R	Appendix L/§416.50(a) Standard: Patient Rights
R	Appendix L/§416.50(b) Standard: Patient Rights
R	Appendix L/§416.50(c) Standard: Patient Rights
R	Appendix L/§416.50(d) Standard: Patient Rights
R	Appendix L/§416.50(e) Standard: Patient Rights
R	Appendix L/§416.50(f) Standard: Patient Rights
R	Appendix L/§416.50(g) Standard: Patient Rights
R	Appendix L/§416.51(b) Standard: Infection Control
N	Exhibit XX Hospital Restraint/Seclusion Death Report Worksheet

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2013 operating budgets.

IV. ATTACHMENTS:

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	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

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

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§482.12 Condition of Participation: Governing Body

There must be an effective governing body **that is** legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body....

Interpretive Guidelines §482.12

The hospital must have **a** governing body **which is effective in carrying out its responsibilities** for the conduct of the hospital. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are **legally** responsible for the conduct of the hospital operations.

If the hospital is part of a healthcare system that includes several separately certified hospitals, each with its own Medicare provider agreement and CMS Certification Number, the governing body of the healthcare system has the option to act as the governing body of each separately certified hospital, unless doing so would conflict with State law. A hospital system also has the option to form several governing bodies, each of which is responsible for several separately certified hospitals. For example, a health system operating hospitals in many states might choose to form regional sub-boards each responsible for the hospitals in its region, or a health system that has a mixture of types of hospitals may choose to form one sub-board responsible for its short-term acute care hospitals and another for its long term care hospitals.

The Medicare program offers hospital facilities considerable flexibility regarding how they choose to participate. Based on the geographic and other institutional limitations set out in the “provider-based” regulation at §413.64, which addresses provider-based status for hospital facilities in multiple locations, hospital governing bodies make business decisions about how they want to participate in Medicare, and they indicate on their Medicare enrollment application the choices they have made. It is not uncommon to find multiple hospital campuses with one owner located in the same geographic area enrolled in Medicare as one hospital. It is also not uncommon to see a hospital system choosing to enroll its various facilities as separately certified hospitals. Various factors enter into consideration when the governing body of a system makes these decisions.

For example, some governing bodies prefer to enroll various campuses as separate hospitals, out of a concern that problems at one hospital’s campus might jeopardize the Medicare participation of the other campuses if they were a multi-campus hospital covered under one Medicare provider agreement. In other cases a governing body may see the benefits of integrating clinical services on multiple campuses into one integrated hospital. In still other

cases, the deciding factor might be the implications for Medicare reimbursement of graduate medical education, the ease of adding satellite locations, etc.

CMS defers to the governing bodies of hospitals to weigh the pertinent factors, the permissible options, and to make business decisions in their best interest when applying to participate in Medicare. CMS's hospital certification decisions and issuance of a provider agreement and associated CCN follow from these business decisions by a hospital's governing body. But once the "hospital," with whatever component parts, has been certified, that hospital must separately demonstrate its compliance with the CoPs, independent of any other facility. (77 FR 29040, May 16, 2012)

If a hospital system has chosen to have a one body act as the governing body for multiple separately certified hospitals, this does not alter the fact that each hospital must separately demonstrate compliance with the CoPs. Examples of what this means include, but are not limited to, the following:

- Each separately certified hospital must be separately and independently assessed for its compliance with the CoPs, through either State Survey Agency or approved national accreditation program surveys. There is no survey of a hospital "system," since the Medicare agreement and its terms are specific to each certified hospital.*
- A system governing body may wish to adopt identical policies and procedures for many aspects of a hospital's operations across all of its hospitals within the system. It has the flexibility to do so, but the documentation of such policies and procedures must be clear that the governing body has chosen to apply them to specifically named hospitals. Also, each hospital must be able to present for inspection the system governing body policies and procedures that clearly apply to that hospital. For example:*

*A document that says "XX Healthsystem has adopted the following policy" is **not** acceptable. Instead, the document must be more specific, such as, "XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C." Furthermore, the names of each hospital (Hospitals A, B, and C in this example) must correspond to the names used for their provider agreements. For example, if Hospital C is one Medicare-certified hospital with two inpatient campuses, one called "East" and one called "West," it is **not** acceptable for the policy document to state, "XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East and Hospital West." It would be acceptable to state, "XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C."*

*It also is **not** acceptable for the policy document to state, "XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East, but not Hospital West." Since "Hospitals" East and West refer to separate campuses of Hospital C, which participates in Medicare as one multi-campus hospital, it is not appropriate to refer to these separate campuses of C as "hospitals," since the XX Healthsystem made a business decision to enroll them as parts of one multi-campus hospital in Medicare. CMS recognizes that, depending on the particular policy topic, it may be acceptable to have policies that vary by type of unit/department within a hospital.*

The system governing body could achieve this as follows: “XX Healthsystem adopts the following policy and procedure requiring that a physician be on-site 24 hours per day, seven days per week on the inpatient campuses of Hospital A and Hospital B, but within Hospital C, only for the East inpatient campus.”

- Likewise, the minutes of the governing body must be written in such a manner so that it is clear when the governing body has taken actions that apply to a specific certified hospital.*
- Departments of separately certified hospitals with one system governing body may not be operationally integrated. For example, if a system has chosen to operate three separately certified hospitals in relatively close proximity to each other rather than to have them certified as one multi-campus hospital, then each hospital must have its own nursing service. It may not have one integrated nursing service with one Director of Nursing who manages one nursing staff for all three hospitals, including moving them back and forth among the different hospitals. The policies and procedures the governing body has adopted for the nursing service in each hospital may be identical, but the services must operate separately. It is also permissible for the same individual to be the Director of Nursing for each hospital, provided that he or she is able to carry out all of the duties of the position in each hospital.*
- Likewise, although the system may choose to operate a quality assessment/performance improvement (QAPI) program at the system level which standardizes indicators measured across system hospitals, each separately-certified hospital in the system must have a QAPI program that is specific to that hospital. This is required not only to demonstrate compliance, but also for the governing body to function effectively, since reviewing QAPI program results only at the system level would make it difficult for the governing body to identify and act upon problems that are localized to one hospital.*

For example, the system may choose to use the same quality indicators or the same methodology to track adverse events across all system hospitals. But each certified hospital must have its own QAPI data with respect to these indicators and adverse events. If a system is tracking readmission rates across all of its hospitals, it must be able to separate out the hospital-specific results for the governing body’s review and possible action.

The governing body must be functioning effectively and holds the ultimate responsibility for the hospital’s compliance not only with the specific standards of the governing body CoP, but also with all of the CoPs. This is the case regardless of whether the regulatory text for a particular condition or standard within a condition specifically mentions responsibilities of the governing body. Substantial, i.e., condition-level, non-compliance with one of the other hospital CoPs may be an indicator that the governing body is not functioning effectively. However, it is not the policy of CMS that condition-level noncompliance with any other CoP automatically results in a condition-level citation of the governing body CoP. Surveyors must consider whether the manner and degree of the other deficiencies provide sufficient evidence to conclude that the governing body is not functioning effectively.

Survey Procedures §482.12

- Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.
- *If the hospital is part of a hospital system which uses one governing body for several of the hospital's separately certified within the system:*
 - *Review the governing body minutes to determine if it is clear which actions pertain to which hospitals.*
 - *Select for review several policy and procedure documents adopted by the system governing body to determine if it is clear that they apply to the hospital being surveyed.*

* * *

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§482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Interpretive Guidelines §482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information needed in order to make "informed" decisions regarding his/her care.

Patient's Representative:

A patient may wish to delegate his/her right to make informed decisions to another person (as allowed under State law).

Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative. Unless prohibited by applicable State law:

- When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the information required to make an informed decision about the patient's care. The hospital must also seek the written consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative by the patient takes precedence over any non-designated

relationship and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.

- In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, the hospital must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The hospital must also seek the consent of the designated individual when informed consent is required for a care decision. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.
- When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient's representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the individual the information required to make informed decisions about the patient's care. The hospital must also seek the consent of the individual when informed consent is required for a care decision. Hospitals are expected to treat the individual as the patient's representative unless:
 - More than one individual claims to be the patient's representative. In such cases, it would be appropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient's representative. The hospital should make its determination of who is the patient's representative based upon the hospital's determination of who the patient would most want to make decisions on his/her behalf. Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient's preferences concerning medical treatment;
 - Treating the individual as the patient's representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient's representative, and may specify when documentation is or is not required; or
 - The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient's spouse, domestic partner, parent or other family member.

Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's representative, given the critical role of the representative in exercising the patient's rights.

A refusal by the hospital of an individual's request to be treated as the patient's representative, based on one of the above-specified familial relationships, must be documented in the patient's medical record must, along with the specific basis for the refusal.

Informed Decisions

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

Hospitals must establish processes to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis, and prognosis.

Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See the guidelines for [42 CFR 482.51\(b\)\(2\)](#) pertaining to surgical services informed consent and the guidelines for [42 CFR 482.24\(c\)\(2\)\(v\)](#) pertaining to medical records for further detail.

Informed decisions related to care planning also extend to discharge planning for the patient's post-acute care. See the guidelines at [42 CFR 482.43\(c\)](#) pertaining to discharge planning for discussion of pertinent requirements.

Hospitals must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.

Required Hospital Disclosures to Patients:

Physician Ownership

In addition, there are certain provisions of the Medicare provider agreement rules concerning disclosures that certain hospitals are required to make which are enforced under [42 CFR 482.13\(b\)\(2\)](#):

- [42 CFR 489.3](#) defines a “physician-owned hospital” as any participating hospital in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the hospital, except for those satisfying an exception found at [§411.356\(a\) or \(b\)](#). *Surveyors are not required to make an independent determination regarding whether a hospital meets the Medicare definition of “physician-owned,” but they must ask whether the hospital is physician-owned.*
- 42 CFR 489.20(u)(1) requires that all physician-owned hospitals provide written notice to their patients at the beginning of each patient’s hospital inpatient stay or outpatient visit stating that the hospital is physician-owned, in order to assist the patient in making an informed decision about his or her care, in accordance with the requirements of §482.13(b)(2).
 - *A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the hospital.*
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the hospital is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the hospital must provide it at the time of the request.
 - However, the notice requirement does not apply to any physician-owned hospital that does not have at least one referring physician (as defined at §411.351) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital. In such cases, the hospital must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the hospital. The hospital must maintain this attestation in its records.
- 42 CFR 489.20(u)(2) provides that physician-owned hospitals must require each physician owner who is a member of the hospital’s medical staff to agree, as a condition of obtaining/retaining medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital their ownership or investment interest in that hospital or that of any immediate family member. The hospital must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital’s policies and procedures governing privileges for physician owners.

- The hospital may exempt from this disclosure requirement any physician owner who does not refer any patients to the hospital.
- [42 CFR 489.12](#) permits CMS to refuse to enter into a provider agreement with a physician-owned hospital applicant that does not have procedures in place to notify patients of physician ownership in the hospital as required under §489.20(u).
- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements at §489.20(u).

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that *if there is no doctor of medicine or osteopathy present in the hospital 24 hours per day, seven days per week, the hospital must provide written notice of this to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of planned or unplanned outpatient visits. The purpose of this requirement is to assist the patient in making an informed decision about his/her care, in accordance with [42 CFR 482.13\(b\)\(2\)](#). Hospitals that have an MD/DO on-site 24/7 (including residents who are MDs or DOs) do not need to issue any disclosure notice about emergency services capability.*

- *The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.*
- *The notice must be provided at the beginning of the planned or unplanned inpatient stay, or outpatient visit subject to notice.*
 - *A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit which is subject to the notice requirement begins at the earliest point at which the patient presents to the hospital.*
- *Individual notices are not required in the hospital's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the DED. The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in [42 CFR 489.24\(b\)](#) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital. If an emergency department patient is determined to require admission, then the individual notice requirements of 42 CFR 489.20(w) would apply to that patient.*
- *Before admitting an inpatient or providing outpatient services requiring notice, the hospital must obtain a signed acknowledgement from the patient stating that he/she understands that*

a doctor of medicine or doctor of osteopathy may not be present at all times services are furnished to him/her.

- In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances, the hospital must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.*
- For a hospital that participates in Medicare with multiple campuses **providing inpatient services (e.g., a main provider campus and separate satellite, remote, and/or provider-based locations)** under one CMS Certification Number, **a separate determination is made for each campus or satellite location with inpatient services as to whether the disclosure notice is required.** For example, if a hospital has **a main campus and a satellite location and a physician is present 24/7 on the main campus but not at the satellite location, the hospital is required to provide the disclosure notice only at the satellite location. No notice is required for patients presenting to the main provider campus in this case. In this same example, if the hospital also has a provider-based, off-campus ambulatory (i.e., same-day) surgery department, no notice is required at that off-campus surgery site, since the hospital's main campus does have an MD/DO present 24/7.***
- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a hospital if the hospital fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/ 7.*

Survey Procedures §482.13(b)(2)

- Is there a hospital policy addressing the patient's or the patient's representative (as appropriate) right to make informed decisions?
 - Does the hospital's policy provide for determining when a patient has a representative who may exercise the patient's right to make informed decisions, and who that representative is, consistent with this guidance and State law?
 - Is there a hospital policy addressing the patient's right to have information on his/her medical status, diagnosis, and prognosis? Does it articulate the hospital's process for assuring that patients have this information?
 - Is there a hospital policy addressing how the patient will be involved in his/her care planning and treatment?
- Is there evidence that the hospital routinely complies with its policies? Evidence would be obtained through review of medical records, interviewing current patients and/or interviewing hospital personnel to determine their understanding of the hospital's informed decision-making policies and how they are implemented. Review of evidence would be designed to determine whether patients/patient representatives are provided adequate

information about the patient's medical status, diagnosis, and prognosis, and then allowed to make informed decisions about their care planning and treatment.

Assessing Required Disclosures:

Physician Ownership

- If the hospital indicates that it is physician-owned but is exempt *under §489.20(v)* from the disclosure requirement *of §489.20(u)(2)*, ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member has an ownership/investment interest in the hospital. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the hospital would not be cited.)
- *If the hospital is physician-owned but not exempt from the physician ownership disclosure requirements:*
 - *Verify that appropriate policies and procedures are in place to assure that necessary written notices are provided to all patients at the beginning of an inpatient or outpatient stay.*
 - *Review the notice the hospital issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the hospital meets the Federal definition of “physician-owned,” that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such a list is provided to the patient at the time the request is made by or on behalf of the patient.*
 - *Determine through staff interviews, observation, and a review of policies and procedures whether the hospital furnishes its list of physician owners and investors at the time a patient or patient’s representative requests it.*
 - *Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned hospital’s medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the hospital agree to provide written disclosure of their own or any immediate family member’s ownership or investment interest to all patients at the time of the referral to the hospital.*

MD/DO 24/7 On-Site Presence

- Determine *through interviews, observation, and medical record review* whether an MD/DO is *present in the hospital, at each campus or satellite location providing inpatient services 24 hours/day, seven days/week.*
- *For each required location where an MD/DO is not present:*

- Verify that the appropriate policies and procedures *are* in place to *assure* written notices *that an MD/DO is not present at all times are* provided at the beginning of an inpatient stay or outpatient *stay to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia.*
- *Verify that there is signed acknowledgment by patients of such disclosure, obtained by the hospital prior to the patient's admission or before applicable outpatient services were provided.*
- *Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the hospital.*
- Verify that the *hospital's emergency department has signage with the appropriate disclosure information.*
- Review the notice the *hospital issues to verify that it indicates how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that hospital, including any remote location or satellite.*

* * *

A-0213

§482.13(g) Standard: Death Reporting Requirements: - Hospitals must report deaths associated with the use of seclusion or restraint.

(1) *With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:*

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, *regardless of the type(s) of restraint used on the patient during this time.* "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation....

(3) *The staff must document in the patient's medical record the date and time the death was:*

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or....

Interpretive Guidelines §482.13(g)(1) & (3)(i)

The hospital must report to its CMS Regional Office each death that occurs:

- While a patient is in restraint or in seclusion, *except when no seclusion has been used and the only restraint used was a soft, cloth-like two-point wrist restraints*;
- Within 24 hours after the patient has been removed from restraint or seclusion, *except when no seclusion has been used and the only restraint used was a soft, two-point wrist restraint*; or,
- Within 1 week after use of restraint or seclusion where *the death is known to the hospital and* it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient's death, *regardless of the type(s) of restraint used on the patient during this time.*
 - “Reasonable to assume” applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued.
 - *This criterion applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was discontinued, and it is reasonable to assume the use of the restraint or seclusion contributed to the patient's death. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient's death was not caused by the use of restraints.*
 - In cases involving death within one week after use of restraint or seclusion where the intervention may have contributed to the patient's death, it is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death.

See the guidance for §482.13(g)(2) for handling of deaths while a patient was in, or within 24 hours after removal of a soft, two-point wrist restraint, when no other restraint or seclusion was used.

The reports *required under §482.13(g)(1)* must be submitted to the CMS Regional Office by telephone, *facsimile, or electronically, as determined by the Regional Office* no later than close of the next business day following the day in which the hospital knows of the patient's death. *The report must include basic identifying information related to the hospital, the patient's name, date of birth, date of death, name of attending physician/practitioner, primary diagnosis(es),*

cause of death (preliminary, in case a final, official cause of death is not yet available), and type(s) of restraint or seclusion used. CMS makes a standard form available for hospitals to use in submitting the required reports.

Hospitals must document in the patient's medical record *the date and time each reportable death associated with the use of restraint or seclusion was reported* to the CMS Regional Office.

After reviewing the submitted information, the Regional Office will determine whether an on-site investigation of the circumstances surrounding the patient's death is warranted and will direct the State Survey Agency to conduct a survey if applicable.

Survey Procedures §482.13(g)(1) & (3)(i):

- Does the hospital have *restraint/seclusion death reporting policies and procedures* that address *responsibilities and systems for identifying restraint/seclusion-associated deaths reportable to CMS and for implementing the reporting and recordkeeping requirements?*
- *Can the hospital provide examples of restraint/seclusion-associated deaths that were reported to CMS?*
 - *If yes, review the report and medical records to determine whether:*
 - *the reports met the criteria for reporting to CMS;*
 - *were submitted timely to CMS;*
 - *were complete; and*
 - *the date and time the death reported to CMS was entered into the patient's medical record.*
 - *If no:*
 - *Ask the hospital how it ensures that there were no reportable restraint/seclusion-associated deaths.*
 - *If the hospital's system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death. Ask if there have been any patient deaths that meet the reporting requirements.*
- *Interview staff in various types of inpatient units, including a psychiatric unit if applicable, to determine whether they are aware of any patients who died while in restraints or seclusion or within one day of restraint or seclusion discontinuation, excluding cases involving only the use of two-point soft wrist restraints and no seclusion. If yes, check whether the hospital has any evidence that these cases were reported to CMS.*

A-0214

(Rev.)

§482.13(g) Standard: Death Reporting Requirements: [- Hospitals must report deaths associated with the use of seclusion or restraint.]

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) [The staff must document in the patient's medical record the date and time the death was:]

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

Interpretive Guidelines §482.13(g)(2), (3)(ii), & (4)

Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:

- **While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and**

- Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion.

Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:

- Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or
- Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death.

The death report log or tracking system entry must include:

- the patient's name;
- patient's date of birth;
- patient's date of death;
- name of the attending physician or other licensed independent practitioner who is responsible for the care of the patient;
- patient's medical record number; and
- primary diagnosis(es).

Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths. Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly. For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance. On the other hand, a rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized.

The log or tracking system must be available in written, i.e., hard copy, or electronic form immediately upon CMS's request. CMS will specify the form in which the information is to be provided. Generally CMS would request access to the log or tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements. However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress. Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare

hospital accreditation program are also entitled to immediate access to the log or tracking system.

The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Survey Procedures §482.13(g)(2), (3)(ii), & (4)

- *Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and recordkeeping requirements?*
- *Ask the hospital how it ensures that each death that must be captured in the log/tracking system is identified and entered.*
- *Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance. If yes, ask the hospital to demonstrate that it has recorded such deaths.*
- *If the hospital's log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death.*
- *Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:*
 - *Each entry was made within 7 days of the patient's death; and*
 - *Each entry contains all the information required under the regulation.*
- *Is the hospital able to make the log or tracking system available immediately on request?*
- *Review a sample of medical records of patients whose deaths were entered in the log or tracking system.*
 - *Does the medical record indicate that only soft, 2-point wrist restraints were used?*
 - *Is there documentation in the medical record of the entry into the log or tracking system?*

A-0347

(Rev.)

§482.22(b) Standard: Medical Staff Organization and Accountability

The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.

- (1) The medical staff must be organized in a manner approved by the governing body.**
- (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.**
- (3) The responsibility for organization and conduct of the medical staff must be assigned only to *one of the following*:**
 - (i) An individual doctor of medicine or osteopathy.***
 - (ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.***
 - (iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.***

Interpretive Guidelines §482.22(b)

The conditions of participation create a system of checks and balances within an overall framework of collaboration between the governing body and the medical staff (and, to a certain degree, also between an individual practitioner and the hospital's medical staff and governing body). Each has its own areas of authority. The medical staff has oversight of all practitioners practicing in the hospital through processes such as peer review and making recommendations concerning privileging and re-privileging. The governing body has the authority to establish the categories of healthcare professionals (regardless of the terms used to describe those categories) who are eligible for privileges and medical staff appointment. However, the governing body must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make their recommendations before the governing body makes a final decision to appoint or not appoint a practitioner to the medical staff. (77 FR 29042 May 16, 2012)

Leadership of the medical staff

The members of the hospital's medical staff must select, in accordance with the medical staff bylaws, rules or regulations approved by the governing body, a single individual to lead the

medical staff and be responsible for the organization and conduct of the medical staff. This individual must be a doctor of medicine or osteopathy, or, if permitted by State law where the hospital is located, a doctor of dental surgery, dental medicine, or podiatric medicine. Removal of the leader of the medical staff may only occur in accordance with medical staff bylaws, rules or regulations.

Executive Committee

The medical staff bylaws, rules and regulations may provide for the members of the medical staff to select a smaller executive committee to which it delegates many of the functions of the medical staff, in order to increase the efficiency of its operations. If the medical staff has an executive committee, the majority of the members must be doctors of medicine (MDs) or osteopathy(DOs).

Accountability of the medical staff

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients. *The medical staff demonstrates its accountability through its exercise of its duties related to appointment of members of the medical staff, its conduct of reappraisals, including peer reviews, its approval of policies and procedures as required under other conditions of participation and its leadership participation in the organization and implementation of the hospital's quality assessment and performance improvement program required in accordance with §482.21.*

Survey Procedures §482.22(b)

- Verify that the medical staff has a formal, *organized* structure *reflected in the medical staff bylaws, rules and regulations and that functions and responsibilities within the medical staff and with respect to* the governing body and other parts of the *hospital are reflected.*
- If there is a *medical staff* executive committee, verify that a majority of the members are doctors of medicine or osteopathy.
- Verify that an individual doctor of medicine or osteopathy, *or if permitted by State law, a doctor of dental surgery, dental medicine, or podiatric medicine, selected by the medical staff,* is responsible for the conduct and organization of the medical staff.
- *Ask the CEO and medical staff leadership to describe the mechanisms by which the medical staff fulfills its responsibility to be accountable for the quality of medical care in the hospital.*

- *Interview several members of the medical staff, including both practitioners who hold leadership or executive committee positions and ones who do not. Ask them what their medical staff duties and responsibilities are and how they perform them. Ask them to describe how the medical staff is accountable for the quality of medical care provided to patients.*

* * *

A-0358

(Rev.)

[The bylaws must:]

482.22(c)(5) Include a requirement that --

- (i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.**

Interpretive Guidelines §482.22(c)(5)(i)

The purpose of a medical history and physical examination (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.

The Medical Staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services. The H&P may be handwritten or transcribed, but always must be placed within the patient's medical record within 24 hours of admission or registration, or prior to surgery or a procedure requiring anesthesia services, whichever comes first.

An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis. (71 FR 68676) An H&P that is completed within 24 hours of the patient's admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.

The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Section 1861(r) defines a physician as a:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; or a
- Chiropractor.

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a “physician.” *For example, a chiropractor is considered a physician only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation).*

Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR 68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient’s hospital admission or registration by a physician who may not be a member of the hospital’s medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulations. Generally, this occurs where the H&P is completed in advance by the patient’s primary care practitioner. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P. (71 FR 68675) (See discussion of H&P update requirements at 42 CFR 482.22(c)(5)(ii).)

Surveyors should cite noncompliance with the requirements of 42 CFR 482.22(c)(5) for failure by the hospital to comply with any of this standard’s components.

Survey Procedures §482.22(c)(5)(i)

- Review the medical staff bylaws to determine whether they require that a physical examination and medical history be done for each patient no more than 30 days before or 24 hours after admission or registration by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. Verify whether the bylaws require the H&P be completed prior to surgery or a procedure requiring anesthesia services.
- Review the hospital's policy, if any, to determine whether other qualified licensed individuals are permitted to conduct H&Ps to ensure that it is consistent with the State's scope of practice law or regulations.
- Verify that non-physicians who perform H&Ps within the hospital are qualified and have been credentialed and privileged in accordance with the hospital's policy.
- Review a sample of inpatient and outpatient medical records that include a variety of patient populations undergoing both surgical and non-surgical procedures to verify that:
 - There is an H&P that was completed no more than 30 days before or 24 hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring anesthesia services; and
 - The H&P was performed by a physician, an oromaxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy.

* * *

A-0396

(Rev.)

§482.23(b)(4) - The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. *The nursing care plan may be part of an interdisciplinary care plan.*

Interpretive Guidelines §482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). *The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, and updating or revising the patient's nursing care plan in*

response to assessments. The nursing care plan is part of the patient's medical record and must comply with the *medical records* requirements at §482.24.

Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

The required documentation for the nursing component of an interdisciplinary care plan remains the same. For other components, the hospital should follow the current documentation policies that it uses to document services provided by other disciplines, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others. Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that the hospital might want to establish. The documentation must also comply with the requirements of the medical records requirement at §482.24. (77 FR 29049, May 16, 2012)

Survey Procedures §482.23(b)(4)

Select a sample of nursing *or interdisciplinary* care plans. Approximately 6-12 plans should be reviewed. *For each plan reviewed, with respect to the nursing care component:*

- *Was the plan* initiated as soon as possible after admission for each patient?
- Does the *plan* describe patient goals *as part of the patient's nursing care assessment* and, as appropriate, physiological and psychosocial factors and patient discharge planning?
- Is *the* plan consistent with the plan for medical care *of the practitioner responsible for the care of the patient*?
- *Is there evidence of reassessment of the patient's nursing care needs and response to nursing interventions and, as applicable, revisions to the plan?*
- *Was the* plan implemented in a timely manner?

* * *

A-0405

(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations....

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.¹ *It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).*² Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration by or under the supervision of nursing or other personnel in accordance with:

- Federal and State law;
- Accepted standards of practice;
- Orders of the practitioner(s) responsible for the patient's care, as specified under §482.12(c) *or of another practitioner as permitted under State law, hospital policy and medical staff bylaws, rules and regulations*; and
- Medical staff-approved policies and procedures.

¹ Institute of Medicine. Preventing Medication Errors. Washington DC: The National Academies Press, 2007.

² Lucado, Jennifer, et al, *Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments*. Statistical Brief #109, April, 2011. Healthcare Cost and Utilization Project, Agency For Healthcare Research and Quality, Rockville, MD.

Federal and State Law

Federal law regulates the approval and classification of drugs and biologicals. Individual States establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals, including which medications they may prescribe and administer, including controlled substances.

Accepted Standards of Practice

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration. Examples of such organizations include, but are not limited to:

- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);
- Institute for Healthcare Improvement (<http://www.ihl.org/ihl>) ;
- U.S Pharmacopeia (www.usp.org) ;
- Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;
- Infusion Nurses Society (<http://www.ins1.org>).

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Orders of **an authorized** practitioner

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.) Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with §482.12(c). However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations. This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least the following:

- Name of the patient;
- Age and weight of the patients, or other dose calculation requirements, when applicable;
- Date and time of the order;
- Drug name;
- Dose, frequency, and route;
- Exact strength or concentration, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and
- Name of the prescriber.

Medical Staff Approved Policies and Procedures

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures. The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

Personnel authorized to administer medication

Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to prepare and administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel preparing and administering drugs and biologicals.

Medication preparation and administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication preparation and administration may include but are not limited to the following:

- Safe handling and preparation of authorized medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;
- Equipment, devices, special procedures, and/or techniques required for medication administration;

Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The hospital's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication:

- the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient;
- the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize

nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications not eligible for scheduled dosing times

The policies and procedures must identify medications which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (prn doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications. For example, medications prescribed for

BID (twice a day) administration might, under a given hospital's policies and procedures, be scheduled to be administered at 8am and 8pm. Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital's pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the hospital's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, hospital policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication;
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.
- Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours.

Missed or late administration of medications

The hospital's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at §482.25(b)(6). See interpretive guidance at §482.25(b)(6) for more details on internal reporting requirements

Evaluation of medication administration timing policies

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Consistent with the QAPI requirements at 42 CFR 482.21(c)(2), medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Survey Procedures §§482.23(c)(1), (c)(1)(i), and (c)(2)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- *Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners.*
- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
 - Verify nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice.
 - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules and regulations. Use the above procedures to determine compliance.
- Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.
 - Verify that the hospital has, consistent with its policies, identified medications: which are:
 - not eligible for scheduled dosing times;
 - Eligible for scheduled dosing times and are time-critical; and
 - Eligible for scheduled dosing times and are not time-critical.
 - Verify the hospital has established total windows of time that do not exceed the following:
 - 1 hour for time-critical scheduled medications
 - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and
 - 4 hours for medications prescribed for daily or longer administration intervals.
 - Verify that the hospital's policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation- specific?
- Review a sample of medical records to determine whether medication administration conformed *to an authorized* practitioner's order, i.e., that *there is an order from an authorized practitioner, or an applicable standing order, and that the* correct medication

was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures. Check that the practitioner's order was still in force at the time the drug was administered.

- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.
 - Is the patient's identity confirmed prior to medication administration?
 - Are procedures to assure the correct medication, dose, and route followed?
 - Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?
 - Does the nurse remain with the patient until medication is taken?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
 - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
 - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?

A-0406

(Rev.)

§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

§482.23(c)(3) - With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under §482.12(c)...

§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.23(c)(1) (ii),(c)(3) and (c)(3)(iii)

All orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, must be documented and signed by a practitioner who is responsible for the care of the patient, as specified under §482.12(c), *or who is another practitioner who is authorized by hospital policy and medical staff bylaws, rules and regulations, and who is acting in accordance with State law, including scope of practice laws.*

Flu and pneumonia vaccines

Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy, *i.e., hospital policy approved by the physician members of the medical staff. There must be an assessment of contraindications prior to administration of the vaccine(s). There is no requirement for authentication by a practitioner when influenza and pneumococcal vaccines are administered to a patient in accordance with hospital policy and State law.*

Standing orders

Nurses or other personnel authorized by hospital policy and in accordance with State law may administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols for patient orders, collectively referred to in this guidance as “standing orders,” to address well- defined clinical scenarios involving medication administration. The requirements governing the hospital’s development and use of standing orders are found at the Medical Records CoP, under §482.24(c)(3). For the nursing services requirement under §482.23(c)(1) (ii), compliance assessment focuses on whether nurses comply with the hospital’s established standing orders policies and procedures when administering drugs or biological in accordance with a standing order.

Survey Procedures §482.23(c)(1) (ii), (c)(3) and (c)(3)(iii)

- Review the hospital’s policy for drug and biological orders. Does it require that *all administration of drugs or biologicals be based on either an applicable standing order or the order of a practitioner who is responsible for the care of the patient or otherwise* authorized by hospital *and medical staff* policy and in accordance with State law to write orders?
- *Interview nursing staff to determine whether they initiate medications in accordance with standing orders. Are they familiar with the hospital’s policies and procedures for using standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.*

- Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records.
- Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, are *included* in the patient's medical record and *authenticated* by a practitioner who is authorized to write orders by hospital *and medical staff* policy and in accordance with State law *and who is responsible for the care of the patient*.
- *Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.*
- Determine whether all orders for drugs and biologicals contain the required elements.

A-0407

(Rev.)

§482.23(c)(3)(i) - If verbal orders are used, they are to be used infrequently.

Interpretive Guidelines §482.23(c)(3)(i)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders must not be a common practice. Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event. Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into an electronic prescribing system without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR 68679)

Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, such as *policies which*:

- Describe *situations in which verbal orders may be used as well as* limitations or prohibitions on their use;
- Provide a mechanism to *establish the identity and authority of* the practitioner issuing a verbal order;
- List the elements required for inclusion in the verbal order process;

- Establish protocols for clear and effective communication *and* verification of verbal orders.

The content of verbal orders must be clearly communicated. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order. (71 FR 68680) As required by §482.24(b), all verbal orders must be promptly documented in the patient's medical record by the individual receiving the order.

Survey Procedures §482.23(c)(3)(i)

- Are there policies and procedures in place to minimize the use of verbal orders?
- Interview direct care staff to determine whether actual practice is consistent with verbal order policies and procedures.
- Review both open and closed patient medical records for the use of verbal orders.
- Were the policies and procedures for the use of verbal orders followed?
- Does the number of verbal orders found in the sampled records suggest routine use, which the regulations do not permit? The number of verbal orders is not in itself evidence of noncompliance, but should result in more focused analysis. For example:
 - Is there a pattern to the use of verbal orders? Some patterns might make sense – e.g., for orders entered between midnight and 7:00 a.m., it might be plausible that it was impossible for the prescribing practitioner to write/computer-enter the order. On the other hand, if one patient care unit has a high proportion of verbal orders, while another does not, this might be a flag for inconsistent implementation of the hospital's policies and procedures for verbal orders.
 - Are verbal orders used frequently for certain types of situations, and if so, is it reasonable to assume that it is impossible or impractical for the prescribing practitioners to write/enter the orders in such situations?
 - Do certain practitioners use verbal orders frequently? From the limited number of records sampled it may be difficult to detect trends related to specific practitioners, but if a surveyor finds such evidence, further investigation is warranted to determine if it is evidence of noncompliance.

A-0408

(Rev.)

§482.23(c)(3)(ii) - When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

Interpretive Guidelines §482.23(c)(3)(ii)

A verbal order for drugs and biologicals may only be accepted by *an individual* who is permitted by Federal and State law and hospital policy to accept verbal orders. Consistent with the requirements of §482.24(b), the *person who received the verbal order* must promptly document *it* in the medical record.

Survey Procedures §482.23(c)(3)(ii)

- Determine whether the hospital has policies and procedures, *consistent with Federal and State law*, governing who is authorized to accept verbal orders.
- Review open and closed patient medical records containing verbal orders for drugs and biologicals. Determine whether the orders *were accepted and* documented by authorized hospital personnel.
- Interview several direct care staff to determine if they are permitted to take verbal orders for drugs and biologicals, and determine whether such staff have been authorized to do so in accordance with hospital policy.

A-0409

(Rev.)

§482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

Interpretative Guidelines §482.23(c)(4)

Generally intravenous (IV) medications and blood transfusions are administered to patients by *registered nurses (RNs)*, consistent with State law governing scope of practice, and approved medical staff policies and procedures. Education and training regarding these procedures are typically included in the nurse's hospital orientation. Nursing staff who receive training for

intravenous medication administration and/or blood transfusion administration during hospital orientation or during other continuing education programs would meet the requirements of this regulation. *Other non-physician personnel, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with State law, including scope of practice law, and the hospital's approved medical staff policies and procedures. (77 FR 29050, May 16, 2012)*

The *appropriate* competencies must be documented in the *qualified staff person's employee* record. Content of the training is based on nationally recognized standards for intravenous medication administration and blood transfusion and must address at least the following: fluid and electrolyte balance; venipuncture techniques, including both demonstration, and supervised practice; and, for blood transfusion training: blood components; blood administration procedures based on hospital policy, State law, and nationally recognized standards of practice; requirements for patient monitoring, including frequency and documentation of monitoring; the process for verification of the right blood product for the right patient; and identification and treatment of transfusion reactions.

All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

Survey Procedures §482.23(c)(4)

- Review a sample of medical records.
 - Are blood transfusions and IV medications administered in accordance with State law and approved hospital and medical staff policies and procedures?
 - Determine the identity of staff who administered blood components and/or IV medications and review their employee records.
 - Are blood transfusions and IV medications administered by personnel who are working within their scope of practice in accordance with State law and hospital and medical staff policies?
 - *Is there evidence that the competency of these staff was assessed with respect to:*
 - *Maintaining fluid and electrolyte balance;*
 - *Venipuncture techniques;*
 - *With respect to blood transfusions:*
 - *Blood components;*

- *Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice;*
- *Patient monitoring requirements, including frequency and documentation of monitoring;*
- *Process for verification of the right blood product for the right patient; and*
- *Transfusion reactions: identification, treatment, and reporting requirements.*

A-0410

(Rev.)

§482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §482.23(c)(5)

Adverse drug reactions and drug administration errors

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).

Transfusion reactions

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

Transfusion reactions are serious and can be life-threatening. The hospital must have policies and procedures in place for the internal reporting of transfusion reactions. The policies must

include procedures for reporting transfusion reactions immediately to the practitioner responsible for the care of the patient. The transfusion reaction must also be reported to the hospital-wide quality assessment performance improvement program as an adverse event, in accordance with the QAPI CoP at 42 CFR 482.21(c)(2). The transfusion reaction must be documented in the patient's medical record, including the prompt notification of the responsible practitioner.

Survey Procedures §482.23(c)(5)

- *For adverse drug events and medication administration errors, follow the survey procedures for §482.25(b)(6). Deficiencies are to be cited under both §482.23(c)(5) and §482.25(b)(6) when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.*
- Request the hospital *policy and* procedure for *internal reporting of* transfusion reactions.
 - *Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital's policies.*
 - *Ask to see if there are any transfusion-related incident reports. Is there evidence that the transfusion reaction was reported immediately to the practitioner responsible for the patient's care? Was it reported to the hospital's QAPI program?*

A-0412

§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

- (i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:*

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

Interpretative Guidelines §482.23(c)(6)(i)

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of hospital-issued medications. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to self-administer their medications.

A hospital program for patient self-administration of hospital-issued medications could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program. Generally such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of hospital-issued medications by outpatients or their caregivers/support persons.

Among the potential benefits of medication self-administration, teaching patients or their caregivers/support persons adherence to the proper medication regimen could reduce hospital inpatient length of stay and also might have a positive effect on continued compliance with the regimen after discharge, potentially avoiding an emergency department visit or inpatient readmission secondary to post-hospital patient medication administration errors and noncompliance.

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person). A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient. A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge, or because the manner in which they must be administered does not lend itself to safe self-administration. (77 FR 29052, May 16, 2012) It must be clear in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of hospital-issued medications.

It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures governing self-administration of hospital-issued medications which are approved by the governing body.

Required elements of a self-administration program:

If the hospital chooses to develop programs for self-administration of hospital-issued medications by patients (and/or their caregiver/support persons), the following must be in place:

- ***An order allowing the patient to administer hospital-issued medications.*** The order must be consistent with the hospital's policy concerning self-administration of hospital-issued

medications and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations.

- **A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer medications for which self-administration has been authorized.** Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support person's) capacity to safely self-administer medications. The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration. The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication. For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient who is administering medications to the patient may for whatever reasons, not be available and a scheduled medication dose is close to being overdue.
- **Instruction in self-administration.** As part of the assessment of the patient's self-administration capacity, nurses are expected to identify the patient's (or the patient's caregiver/support person's) education and/or training needs. These needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs, and how they were addressed, must be documented in the medical record.
- **Security of the self-administered medications.** The security of a patient's self-administered medications is extremely important, but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.

Note that Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are

considered secure despite their use of controlled substances.

Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security. (77 FR 29052, May 16, 2012)

- **Documentation of medication administration.** *Under the regulation, a nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.*

Survey Procedures §482.23(c)(6)(i)

If the hospital permits patient self-administration of hospital-issued medications:

- *Ask the hospital to identify current inpatients for whom self-administration of hospital-issued medications is permitted.*
 - *Interview of several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications*
 - *Interview nurses caring for the selected patients. Ask them:*
 - *What the applicable hospital policies and procedures are regarding supervision of self-medication.*
 - *How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?*
 - *How they instruct a patient (or patient's caregiver/support person's) in medication self-administration.*
 - *How self-administered medications are secured.*

- *How they document self-administration of medications.*
- *To provide a copy of the hospital's policies and procedures. Are they following the policies and procedures?*
- *Review the medical records for the selected patients. Is there documentation of:*
 - *An order for self-administration of specific medication(s).*
 - *A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication.*
 - *Documentation of nurse instruction to the patient or (or patient's caregiver/support person) in safe and appropriate techniques for self-administration of medication.*
 - *Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.*
- *Do the hospital's policies and procedures for self-administration of hospital-issued medications address:*
 - *Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration;*
 - *Orders for self-administration of medication;*
 - *Requirements, if any, for supervision of self-administration;*
 - *Assessment of self-medication capacity;*
 - *Instruction in self-medication;*
 - *Security of self-administered medications; and*
 - *Documentation of self-administration.*

* * *

A-0413

[§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.]

§482.23(c)(6)(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

Interpretative Guidelines §482.23(c)(6)(ii)

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of medications the patient brings himself or herself to the hospital. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to retain and self-administer medications they bring with them from home.

A hospital program for patient self-administration of medications the patient brings from home could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program. Generally such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of medications that outpatients or their caregivers/support persons bring with them.

Among the potential benefits of permitting self-administration of medications the patient brings from home is that problems are avoided related to the hospital's formulary not including a particular medication that a patient needs to continue to take during his/her hospital stay, and the patient prefer to avoid medication substitution. The hospital also gains an opportunity to identify suboptimal patient medication administration techniques for these drugs and to provide instruction designed to ensure that the patient is administering his/her medications properly.

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person). A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient. A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge. It must be clear in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of medications the patient brings from home.

It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures for self-administration of medications the patient brings from home which are approved by the governing body.

Required elements of a self-administration program:

If the hospital chooses to develop programs for self-administration of medications brought from home by patients (and/or their caregiver/support persons), the following must be in place:

- ***An order allowing the patient to administer medications brought from home.*** The order must be consistent with the hospital's policy concerning self-administration of medications brought from home and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations.
- ***A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer the medication(s) specified in the order, including a determination whether the patient (or their caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s).*** Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support person's) capacity to safely self-administer medications. The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration. The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. (77 FR 29052, May 16, 2012)

Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication. For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient who is administering medications to the patient may for whatever reasons, not be available and a scheduled medication dose is close to being overdue.

As part of the assessment of the patient's self-administration capacity, nurses are expected to identify whether the patient (or the patient's caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s). Even though the patient has been taking the medication at home, the patient (or the patient's caregiver/support person) may not be using optimal administration techniques. Patient needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs identified, and how they were addressed, must be documented in the medical record.

- ***Identification/visual evaluation for integrity.*** Hospitals must have policies and procedures addressing how they will identify the medications the patient has brought from home. Identification is important because the label on the patient's medication container may not

accurately reflect the contents. Further, the medication might have expired or have not been stored correctly in the patient's home, requiring hospitals to at least conduct a visual inspection to see if the medication appears to have retained its integrity. It is recognized that a visual inspection for integrity may not be definitive, but the regulation does not require use of more complex methods.

- **Security of the self-administered medications.** The security of a patient's self-administered medications is extremely important, but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.

Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications brought from home that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security.

- **Documentation of medication administration.** Under the regulation, a nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.

Survey Procedures §482.23(c)(6) and (c)(6)(i)

If the hospital permits patient self-administration of medications brought from home:

- Ask the hospital to identify current inpatients for whom self-administration of medications brought from home is permitted.
 - Interview of several of these patients (or their caregivers/support persons when applicable) to ask if that they received instruction on how to self-administer their medications consistent with hospital policy.

- Interview nurses caring for the selected patients. Ask them:
 - What the applicable hospital policies and procedures are regarding supervision of self-medication.
 - How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?
 - How they instruct a patient (or patient's caregiver/support person's) in safe and proper medication self-administration when educational needs have been identified.
 - How self-administered medications are secured.
 - How they document self-administration of medications.
 - To provide a copy of the hospital's policies and procedures. Are they following the policies and procedures?
- Review the medical records for the selected patients. Is there documentation of:
 - An order for self-administration of specific medication(s).
 - A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication and identification of whether or not there are educational needs that have been met.
 - Documentation of the identification and visual assessment of medications brought from home.
 - Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.
- Do the hospital's policies and procedures for self-administration of medications brought from home address, consistent with the regulatory requirements, the following:
 - Limitations on medications eligible for self-administration or patient conditions which exclude self-administration;
 - Orders for self-administration of medications brought from home;
 - Requirements, if any, for supervision of self-administration;
 - Assessment of self-medication capacity, including identification of educational needs and how they are to be met;
 - Identification and visual inspection for integrity of self-administered medications brought from home;
 - Security of self-administered medications; and
 - Documentation of self-administration in the medical record?

A-0454

(Rev.)

§482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner *or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.*

Interpretive Guidelines §482.24(c)(2)

The hospital must ensure that all orders, including verbal orders, are dated, timed, and authenticated promptly. The Merriam-Webster online dictionary defines “prompt” as performed readily or immediately.

Verbal orders are orders for medications, treatments, interventions or other patient care that are transmitted as oral, spoken communications between senders and receivers, delivered either face-to-face or via telephone.

The receiver of a verbal order must date, time, and sign the verbal order in accordance with hospital policy. CMS expects hospital policies and procedures for verbal orders to include a read-back and verification process.

The prescribing practitioner must verify, sign, date and time the order as soon as possible after issuing the order, in accordance with hospital policy, and State and Federal requirements.

Authentication of a verbal order may be written, electronic, or faxed. The hospital must have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries.

In some instances, the ordering practitioner may not be able to authenticate his or her *order, including a* verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is “off duty” for the weekend or an extended period of time). In such cases it is acceptable for another practitioner who is responsible for the patient’s care to authenticate the *order, including a* verbal order, of the ordering practitioner *as long as it is permitted under State law, hospital policies and medical staff bylaws, rules, and regulations. Hospitals may choose in their policies to restrict which practitioners it would authorize to authenticate another practitioner’s orders. For example, a hospital could choose to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. (77 FR 29053, May 16, 2012)*

- All practitioners responsible for the patient’s care are expected to have knowledge of the patient’s hospital course, medical plan of care, condition, and current status.
- When a practitioner other than the ordering practitioner *authenticates an* order, that practitioner assumes responsibility for the order as being complete, accurate and final.

- A qualified *non-physician* practitioner, such as a physician assistant (PA) or nurse practitioner (NP), *who is responsible for the care of the patient* may authenticate a physician's or other qualified *non-physician* practitioner's order only if the order is within his/her scope of practice.

If State law requires that the *ordering* practitioner authenticate *his/her own orders, or his/her own* verbal orders, *then* a practitioner other than the prescribing practitioner would not be permitted to authenticate the verbal order in that State.
(71 FR 68682 *and* 77 FR 29053, May 16, 2012)

NOTE CONCERNING VERBAL ORDERS FOR LABORATORY TESTS:

The requirement to authenticate promptly a verbal order applies to verbal orders associated with both inpatients and outpatients. It is possible that a hospital verbal order for a laboratory test could be authenticated in compliance with the Clinical Laboratory Improvement Amendment (CLIA) regulatory standard of authentication, i.e., within 30 days, but nonetheless be out of compliance with the hospital Medical Records Services requirement *for prompt* authentication of *all orders, including* verbal orders. Because CLIA laboratories – even if physically situated in a hospital – are surveyed for compliance only with CLIA regulations, the laboratory would not be cited for a deficiency by a CLIA survey team. However, hospital surveyors conducting a survey would cite the hospital's inpatient or outpatient recordkeeping for deficiencies under the Medical Record Services CoP if the lab order originated for a patient during a hospital inpatient stay or hospital outpatient clinic visit and *the order was not authenticated promptly*.

Survey Procedures §482.24(c)(2)

Does the hospital have policies and procedures requiring prompt authentication of all orders, including verbal orders, by the *ordering* practitioner or, if permitted under State law, *hospital policy and medical staff bylaws, rules and regulations*, another practitioner responsible for the care of the patient?

- Do the hospital's policies and procedures for verbal orders include a "read back and verify" process where the receiver of the order reads back the order to the ordering practitioner to verify its accuracy?

Review orders, including verbal orders, in a sample of medical records. Have orders been dated, timed, and authenticated promptly by the ordering practitioner or, *if permitted under State law, hospital policy and medical staff bylaws, rules and regulations*, another practitioner who is responsible for the care of the patient?

- Has the receiver of a verbal order dated, timed, and signed the order according to hospital policy?

A-0457

(Rev.)

§482.24(c) (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of §482.24(c)(3), particularly with respect to "order sets."

- Not all pre-printed and electronic order sets are considered a type of "standing order" covered by this regulation. Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or other qualified practitioner authorized to write orders, and none of the treatment choices and actions can be initiated by non-practitioner clinical staff before the physician or other qualified practitioner actually creates the patient-specific order(s), such menus would not be

considered “standing orders” covered by this regulation. We note in such cases the menus provide a convenient and efficient method for the physician/practitioner to create an order, but the availability of such menu options does not create an “order set” that is a “standing order” subject to the requirements of this regulation. The physician/practitioner may, based on his/her professional judgment, choose to: use the available menu options to create an order; not use the menu options and instead create an order from scratch; or modify the available menu options to create the order. In each case the physician/practitioner exercises his privileges to prescribe specific diagnosis and/or treatment activities that are to be implemented for a patient.

- On the other hand, in cases where hospital policy permits treatment to be initiated, by a nurse, for example, without a prior specific order from the treating physician/practitioner, this policy and practice must meet the requirements of this regulation for review of standing orders, regardless of whether it is called a standing order, a protocol, an order set, or something else. Such treatment is typically initiated when a patient’s condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a physician or other qualified practitioner prior to the provision of care.*
- Hybrids, where a component for non-practitioner-initiated treatment is embedded within a menu of options for the physician or other qualified practitioner, still require compliance with the requirements for a standing order for that component. For example, if an order set includes a protocol for nurse-initiated potassium replacement, that protocol must be reviewed under the requirements of this regulation before it may become part of a menu of treatment options from which a physician or other qualified practitioner would select treatments for a particular patient.*

Requirements for “Standing Orders”

Hospitals have the flexibility to use standing orders to expedite the delivery of patient care in well-defined clinical scenarios for which there is evidence supporting the application of standardized treatments or interventions.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence, when orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care.

In all cases, implementation of a standing order must be medically appropriate for the patient to whom the order is applied.

Much of the evidence on the effectiveness of standing orders in hospitals has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.)*
- Post-operative recovery areas.*
- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.*

Standing orders may not be used in clinical situations where they are specifically prohibited under Federal or State law. For example, the hospital patient's rights regulation at §482.13(e)(6) specifically prohibits the use of standing orders for restraint or seclusion of hospital patients.

When deciding whether to use standing orders, hospitals should also be aware that, although use of standing orders is permitted under the hospital Conditions of Participation, some insurers, including Medicare, may not pay for the services provided because of the use of standing orders. (77 FR 29056)

Minimum requirements for standing orders. Hospitals may employ standing orders only if the following requirements are met for each standing order for a particular well-defined clinical scenario:

- Each standing order must be reviewed and approved by the hospital's medical staff and nursing and pharmacy leadership before it may be used in the clinical setting. The regulation requires a multi-disciplinary collaborative effort in establishing the protocols associated with each standing order.*
- The hospital's policies and procedures for standing orders must address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or other practitioners responsible for the care of the patient.*
- For each approved standing order, there must be specific criteria clearly identified in the protocol for the order for a nurse or other authorized personnel to initiate the execution of a particular standing order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified. Under no circumstances may a hospital use standing orders in a manner that requires any staff not*

authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.

Since residents are physicians, this regulation does not require specific criteria for a resident to initiate the execution of a particular standing order. However, there may be State laws governing the practice of residents in hospitals that are more restrictive; if so, the hospital is expected to comply with the State law. Likewise, the hospital may choose through its policies and medical staff bylaws, rules and regulations to restrict the role of residents with respect to standing orders.

- Policies and procedures should also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter.*
- Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal vaccines, which do not require such authentication in accordance with § 482.23(c)(2).*

(76 FR 65896, October 24, 2011 & 77 FR 29056, May 16, 2012)

- The hospital must be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the hospital copies, but rather that the content of each standing order in the hospital must be consistent with nationally recognized, evidence-based guidelines for providing care. The burden of proof is on the hospital to show that there is a sound basis for the standing order.*
- Each standing order must be subject to periodic and regular review by the medical staff and the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols. At a minimum, an annual review of each standing order would satisfy this requirement. However, the hospital's policies and procedures must also address a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. The review may be prepared by the hospital's QAPI program, so long as the medical staff and nursing and pharmacy leadership read, review, and, as applicable, act upon the final report. Among other things, reviews are expected to consider:*
 - Whether the standing order's protocol continues to be consistent with the latest standards of practice reflected in nationally recognized, evidence-based guidelines;*

- *Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. Note that the review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition; and*
- *Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.*
- *An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. The hospital must ensure each standing order that has been executed is dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient. Another practitioner who is responsible for the care of the patient may date, time and authenticate the standing order instead of the ordering practitioner, but only if the other practitioner is acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules and regulations.*

The hospital's standing orders policies and procedures must specify the process whereby the responsible practitioner, or another authorized practitioner, acknowledges and authenticates the initiation of each standing order after the fact, with the exception of standing orders for influenza and pneumococcal vaccines, which do not require such authentication. Further, the responsible practitioner must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. The medical record must reflect the physician's actions to modify, cancel, void or refusal to authenticate a standing order that the physician determined was not medically necessary. (76 FR 65896, October 24, 2011)

Survey Procedures §482.24(c)(3)

- *Ask the hospital's medical staff and its nursing and pharmacy leadership whether standing orders are used. If yes, ask them to describe how a standing order is developed and monitored, and their role in the process.*
- *Ask to see an example of one or more standing orders, including documentation on the development of the order, including:*
 - *Reference to the evidence-based national guidelines that support it;*
 - *Participation of medical staff and nursing and pharmacy leadership in the review and approval of the standing order;*

- *Description of the protocol to be followed when initiating the execution of the order, including description of the roles and responsibilities of various types of staff;*
- *Description of the process for authenticating the order's initiation by the practitioner responsible for the care of the patient, or another authorized practitioner;*
- *Evidence of training of personnel on the order's protocol; and*
- *Evidence of periodic evaluation and, if needed, modification of the standing order, including whether the order remains consistent with current evidence-based national guidelines, staff adherence to the protocol for initiation and execution, and whether there have been any preventable adverse events associated with the order.*
- *Ask staff providing clinical services in areas of the hospital where standing orders might be typically used, including but not limited to, the emergency department, labor and delivery units, and inpatient units, whether standing orders are used. If they say yes, ask them:*
 - *To describe a typical scenario where a standing order would be used, and what they would do in that case.*
 - *For a copy of the protocol for that standing order. Does their description conform to the protocol?*
- *Review a sample of medical records of patients where a nurse-initiated standing order was used and verify that the order was documented and authenticated by a practitioner responsible for the care of the patient.*

A-0458

(Rev.)

482.24(c)(4) - All records must document the following, as appropriate:

(i) Evidence of--

- (A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.**

Interpretive Guidelines §482.24(c)(4)(i)(A)

The medical record must include documentation that a medical history and physical examination (H&P) was completed and documented for each patient no more than 30 days prior to hospital admission or registration, or 24 hours after hospital admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services.

The purpose of an H&P is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient.

The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient, or same-day surgeries or procedures. (71 FR 68676) The H&P may be handwritten or transcribed. An H&P that is completed within 24 hours of the patient's admission or registration, but after surgery or a procedure requiring anesthesia would not be in compliance.

Survey Procedures §482.24(c)(4)(i)(A)

Review a sample of inpatient medical records for various types of patients and outpatient medical records for patients having same day surgery or a procedure requiring anesthesia to determine whether:

- There is an H&P that was done no more than 30 days before or 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure;
- The H&P documentation was placed in the medical record within 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure;

A-0461

(Rev)

482.24(c)(4) - [All records must document the following, as appropriate:

(i) Evidence of --]

- (B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.**

Interpretive Guidelines §482.24(c)(4)(i)(B)

When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but, in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure.

The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. The physician, oromaxillofacial surgeon, or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. (71 FR 68676) *Such statements in the medical record would meet the requirement for documenting the H&P update.*

Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

Survey Procedures §482.24(c)(4)(i)(B)

In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration.

- Determine whether an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.
- Determine whether, in all cases involving surgery or a procedure requiring anesthesia

services, the update was completed and documented prior to the surgery or procedure.

A-0463

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(ii) - Admitting diagnosis.

Interpretive Guidelines §482.24(c)(4)(ii)

All inpatient medical records must contain the admitting diagnosis.

Survey Procedures §482.24(c)(4)(ii)

Verify in a sample of medical records that the patient's admitting diagnosis is documented in each medical record.

A-0464

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(iii) - Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

Interpretive Guidelines §482.24(c)(4)(iii)

All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient's medical record in order to be available to the physician or other care providers to use in making assessments of the patient's condition, to justify treatment or continued hospitalization, to support or revise the patient's diagnosis, to support or revise the plan of care, to describe the patient's progress and to describe the patient's response to medications, treatments, and services.

Survey Procedures §482.24(c)(4)(iii)

Review a sample of medical records of patients who have orders for consultative evaluations. Are the results/reports and other clinical findings of those consultative evaluations included in the patient's medical record?

A-0465

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(iv) - Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

Interpretive Guidelines §482.24(c)(4)(iv)

All patient medical records, both inpatient and outpatient, must document:

- Complication;
- Hospital-acquired infections;
- Unfavorable reactions to drugs; and
- Unfavorable reactions to anesthesia.

Survey Procedures §482.24(c)(4)(iv)

Through observations, interviews, and reviews of hospital reports and documentation, determine if patient complications, hospital-acquired infections, unfavorable reactions to drugs/anesthesia have been documented in the applicable patient's medical record.

A-0466

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(v) - Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(4)(v)

Informed consent is discussed in three locations in the CMS Hospital CoPs. See also the guidelines for 42 CFR 482.13(b)(2) pertaining to patients' rights, and the guidelines for 42 CFR 482.51(b)(2), pertaining to surgical services.

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.

Informed Consent Forms

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place;
- Name of the specific procedure, or other type of medical treatment for which consent is being given;
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (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. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
- Signature of the patient or the patient's legal representative; and
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;
- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

Survey Procedures §482.24(c)(4)(v)

- Verify that the hospital has assured that the medical staff has specified which procedures and treatments require written patient consent.
- Verify that the hospital's standard informed consent form contains the elements listed above as the minimum elements of a properly executed informed consent.
- Compare the hospital's standard informed consent form to the hospital's policies on informed consent, to verify that the form is consistent with the policies. If there is applicable State law, verify that the form is consistent with the requirements of that law.
- Review a minimum of six random medical records of patients who have, are undergoing, or are about to under a procedure or treatment that requires informed consent. Verify that each medical record contains informed consent forms.
- Verify that each completed informed consent form contains the information for each of the elements listed above as the minimum elements of a properly executed informed consent, as well as any additional elements required by State law and/or the hospital's policy.

A-0467

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(vi) - All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

Interpretive Guidelines §482.24(c)(4)(vi)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);
- All nursing notes (including nursing care plans);
- All reports of treatment (including complications and hospital-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

Survey Procedures §482.24(c)(4)(vi)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.

- Is *this* information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?
-

A-0468

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(vii) - Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

Interpretive Guidelines §482.24(c)(4)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and hospital policy, who admitted the patient is responsible for the patient during the patient's stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other MD/DOs who work with the patient's MD/DO and who are covering for the patient's MD/DO and who are knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans may write the discharge summary at the responsible MD/DO's request.

In accordance with hospital policy, and [42 CFR Part 482.12\(c\)\(1\)\(i\)](#) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State's regulatory mechanism.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content.

The discharge summary requirement would include outpatient records. For example:

- The outcome of the treatment, procedures, or surgery;

- The disposition of the case;
- Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.

Survey Procedures §482.24(c)(4)(vii)

- Verify that a discharge summary is included to assure that proper continuity of care is required.
 - Verify that a final diagnosis is included in the discharge summary.
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A-0469

(Rev.)

[All records must document the following, as appropriate:]

§482.24(c)(4)(viii) - Final diagnosis with completion of medical records within 30 days following discharge.

Interpretive Guidelines §482.24(c)(4)(viii)

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Survey Procedures §482.24(c)(4)(viii)

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient's final diagnosis?

* * *

A-0508

(Rev.)

§482.25(b)(6) - Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's *quality assessment and performance improvement program*.

Interpretive Guidelines §482.25(b)(6)

Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician

must be notified, the patient's attending physician must be notified as soon as he/she is available. In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

- Drug administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." *In the context of this regulation, however, "drug administration error" is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).*

- Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

- Requires discontinuing the drug (therapeutic or diagnostic)
- Requires changing the drug therapy
- Requires modifying the dose (except for minor dosage adjustments)
- Necessitates admission to a hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis, or
- Results in temporary or permanent harm, disability, or death.

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."

- Drug incompatibilities

A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.

When IV medications are administered with known incompatibilities, an error has occurred and it needs to be reported to the attending physician immediately. Any unexpected reaction that occurs between IV medications not previously identified as incompatible also needs to be reported.

Hospitals can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug manufacturers.

The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.

Drug administration errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician. For example, if an analgesic dose is missed during the night shift, it can be reported first thing in the morning. Hospital staff *is* expected to use their clinical judgment, based on patient presentation and assessment in accordance with hospital policy and procedures, to determine whether immediate reporting is required.

On the other hand, for purposes of reporting to the hospital's QAPI program, hospitals must, in accordance with the requirements of the QAPI CoP at 42 CFR 482.21(c)(2), track and report not only the errors that cause or risk harm to the patient, but also those which do not. Such "near misses" and suspected ADRs may reveal important information about systems vulnerabilities that the hospital should address in order to avoid events that result in harm.

Hospitals must establish policies and procedures for reporting of medication errors, ADRs, and incompatibilities, and ensure that staff *is* aware of the reporting process. For those events that require immediate reporting, the hospital's policies must establish timeframes for reporting that are based on the clinical effect of the error on the patient.

To improve staff willingness to report medication error incidents, hospitals are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or hospital disciplinary action.

In addition to employing broad definitions of medication errors and ADRs for QAPI tracking purposes and encouraging *the* reporting of medication errors, ADRs and drug incompatibilities,

the hospital must take additional steps to identify these events as part of its QAPI program *where medical errors and adverse patient events are measured, analyzed and tracked*. Reliance solely on incident reporting fails to identify the majority of errors and adverse reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of a patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event. The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the QAPI program medication errors and ADRs. Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals. Hospitals are encouraged, and may be required by State law, to participate in statewide and national reporting of drug administration errors, adverse drug reactions, and incompatibilities. National organizations include, but are not limited to, the Food and Drug Administration's (FDA) MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program.

Survey Procedures §482.25(b)(6)

- Does the hospital have policies and procedures that define medications errors, ADRs, and drug incompatibilities? Do they address the circumstances under which they must be reported immediately to the attending physician, as well as to the hospital's QAPI program? Do they address how reporting is to occur?
- Are all medication errors and suspected ADRs promptly recorded in the patient's medical record, including those not subject to immediate reporting?
- If upon review of a sample of records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or covering physician, in accordance with the hospital's written policies and procedures. If it is reported to a covering physician, determine if it was also reported to the attending physician when he/she became available.
- Ask hospital staff what they do when they become aware of a medication error, ADR or drug incompatibility. Are staff aware of and do they follow the hospital's policy and procedures?
- Ask hospital staff how they manage drug incompatibilities. What tools do they use in the clinical setting to minimize the risk of incompatibilities? How is the information related to drug incompatibilities made available to the clinical staff administering IV medications (posters, online tools, etc.)? How often is the information updated to ensure accuracy?
- Interview hospital staff to ascertain awareness of the hospital's policy on reporting and documentation of medication errors and adverse drug reactions.

- How does information regarding medication errors, adverse drug reactions, and incompatibilities get reported to the hospital QAPI program? Ask staff to speak to the process.
- For QAPI reporting purposes, is the hospital's definition of an ADR and medication error based on national standards?

* * *

A-0748

(Rev.)

§482.42(a) Standard: Organization and Policies

A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases....

Interpretive Guidelines §482.42(a)

Hospital infection control officers are often referred to as “hospital epidemiologists (HEs),” “infection control professionals (ICPs)” *or* “*infection preventionists*.” CDC has defined “infection control professional” as “a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.”

The hospital must designate in writing an individual or group of individuals as its infection control officer or officers. In designating infection control officers, hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CBIC), or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians)). Infection control officers should maintain their 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.

CMS does not specify either the number of infection control officers to be designated or the number of infection control officer hours that must be devoted to the infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the infection control program. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers 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 hospitals may find useful.

The infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases. Infection control policies should address the roles and

responsibilities for infection control within the hospital; how the various hospital committees and departments interface with the infection control program; and how to prevent infectious/communicable diseases; and how to report infectious/communicable diseases to the infection control program.

Survey Procedures §482.42(a)

- Determine whether an infection control officer(s) is designated and has the responsibility for the infection prevention and control program.
 - Review the personnel file of the infection control officer(s) to determine whether he/she is qualified through ongoing education, training, experience, or certification to oversee the infection control program.
 - Determine whether the infection control officer(s) have developed and implemented hospital infection control policies.
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A-0749

(Rev.)

§482.42(a)–....The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §482.42(a)

The infection control officer or officers must develop, implement and evaluate measures governing the identification, investigation, reporting, prevention and control of infections and communicable diseases within the hospital, including both healthcare–associated infections and community-acquired infections. Infection control policies should be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated. The successful development, implementation and evaluation of a hospital-wide infection prevention and control program requires frequent collaboration with persons administratively and clinically responsible for inpatient and outpatient departments and services, as well as, non-patient-care support staff, such as maintenance and housekeeping staff.

Implicit in the infection control officer(s)' responsibility for measures to identify, investigate, report, prevent and control infections and communicable diseases are the following activities:

- Maintenance of a sanitary hospital environment;
- Development and implementation of infection control measures related to hospital personnel; hospital staff, for infection control purposes, includes all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers;

- Mitigation of risks associated with patient infections present upon admission:
- Mitigation of risks contributing to healthcare-associated infections:
- Active surveillance;
- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
- Program evaluation and revision of the program, when indicated;
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks;
- Complying with the reportable disease requirements of the local health authority;

For example, a hospital with a comprehensive hospital-wide infection control program should have and implement policies and procedures, based as much as possible on national guidelines, that address the following:

- Maintenance of a sanitary physical environment:
 - Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;
 - Maintaining safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and airborne infection isolation rooms;
 - Techniques for food sanitation;
 - Techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture;
 - Techniques for textiles reprocessing, storage and distribution;
 - Techniques for disposal of regulated and non-regulated waste; and
 - Techniques for pest control.
- Hospital staff-related measures:
 - Measures – and authority - for evaluating hospital staff immunization status for designated infectious diseases, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);

- Policies articulating the authority and circumstances under which the hospital screens hospital 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 hospital staff are restricted from providing direct patient care and/or are required to remain away from the healthcare 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;
- Measures to evaluate staff and volunteers exposed to patients with infections and communicable disease;
- Mitigation of risks associated with patient infections present upon admission:
 - Measures for the early identification of patients who require isolation in accordance with CDC guidelines;
 - Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices;
 - Use and techniques for “isolation” precautions as recommended by the CDC.
- Mitigation of risks contributing to healthcare-associated infections:
 - Surgery-related infection risk mitigation measures:
 - Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as a protocol to assure that antibiotic prophylaxis to prevent surgical site infection 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 and invasive procedures performed outside the operating room, including sterilization of instruments;
 - Other hospital healthcare-associated infection risk mitigation measures:
 - Promotion of handwashing hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;
 - Measures specific to prevention of infections caused by organisms that are antibiotic-resistant;

- Measures specific to prevention of device-associated bloodstream infection (BSI), such as a protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when a line is no longer needed;
- Measures specific to prevention of other device-associated infections, e.g., those associated with ventilators, tube feeding, indwelling urinary catheters, etc;
- Isolation procedures and requirements for highly immuno-suppressed patients who require a protective environment.
- Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection;
- Requiring disinfectants, antiseptics, and germicides to be used in accordance with the manufacturers' instructions;
- Appropriate use of facility and medical equipment, including negative and positive pressure isolation room equipment, portable air filtration equipment, treatment booths and enclosed beds, UV lights, and other equipment used to control the spread of infectious agents;
- Adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations, for infections/communicable diseases identified as present in the hospital; and
- Educating patients, visitors, caregivers, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the hospital and in the community;
- Active surveillance:
 - *The hospital is expected to identify and track infections and communicable diseases in any of the following categories occurring throughout the hospital, whether in patients or staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers). Hospitals are not required to organize their surveillance according to these categories. The categories are:*
 - *Healthcare-associated infections selected by the hospital's Infection Prevention and Control Program as part of a targeted surveillance strategy based on nationally recognized guidelines and periodic risk assessment;*
 - *Patients or staff with identified communicable diseases that local, State, or Federal health agencies require be reported;*

- *Patients identified by laboratory culture as colonized or infected with multi-drug-resistant organisms (MDROs), as defined by the hospital's Infection Prevention and Control Program;*
- *Patients who meet CDC criteria for requiring isolation precautions (other than "Standard Precautions" or a protective environment) during their hospitalization;*
- *Patients or staff with signs and symptoms that have been requested be reported or recorded by local, State, or Federal health agencies; and*
- *Staff or patients who are known or suspected to be infected with epidemiologically-significant pathogens that are identified by the hospital or local, State, or Federal health agencies.*

For Information – Not Required/Not to be Cited

Many hospitals are using automated surveillance technology (AST) or "data mining" for identification and control of hospital-acquired infections (HAI) and implementation of evidence-based infection control practices. Use of AST or similar technology is encouraged in hospitals, but is not required.

- Provisions to monitor compliance with all policies, procedures, protocols and other infection control program requirements;
- Provision for program evaluation and revision of the program, when indicated;
- Policies and procedures developed in coordination with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and
- Procedures for meeting the reporting requirements of the local health authority.

Survey Procedures §482.42(a)

- Determine whether the hospital has an active, hospital-wide infection control program reflecting the infection control officer responsibilities specified in the interpretive guidelines. Specifically, surveyors should determine whether the hospital:
 - Maintains a sanitary environment;
 - Develops and implements infection control measures related to hospital personnel;

- Mitigates risks associated with patient infections present upon admission;
- Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand washing hygiene);
- Conducts active surveillance;
- Monitors compliance with all infection control program requirements;
- Evaluates the infection control program regularly and revises it, when indicated;
- Coordinates as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and
- Complies with the reportable disease requirements of the local health authority.

* * *

A-0756

(Rev.)

§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services

The chief executive officer, the medical staff, and the director of nursing must--

- (1) Ensure that the hospital-wide quality *assessment and performance improvement (QAPI)* program and training programs address problems identified by the infection control officer or officers; and**
- (2) Be responsible for the implementation of successful corrective action plans in affected problem areas.**

Interpretive Guidelines §482.42(b)

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program.

To reflect the importance of infection control the regulations specifically require that the hospital's QAPI and training programs must be involved in addressing problems identified by the infection control program, and hold the CEO, medical staff and DON jointly responsible for linking the infection control program with the QAPI and training programs. Requirements for the hospital's QAPI program are found at 42 CFR 482.21.

These hospital leaders are also held explicitly responsible for implementing successful corrective action plans. In order to accomplish this, hospital leaders must monitor adherence to corrective action plans, as well as assess the effectiveness of actions taken, with implementation of revised corrective actions as needed.

Education on the principles and practices for preventing transmission of infectious agents within the hospital should be provided to anyone who has an opportunity for contact with patients or medical equipment, e.g., nursing and medical staff; therapists and technicians, such as those involved in respiratory, physical, and occupational therapy and radiology and cardiology services; phlebotomists; housekeeping and maintenance staff; volunteers; and all students and trainees in healthcare professions.

Survey Procedures §482.42(b)

- Determine whether the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s).
- Determine whether infection control problems identified are reported to the Medical Staff, CEO and DON. Verify that hospital leadership takes steps to assure that corrective actions are implemented and successful.

A-1076

(Rev.)

§482.54 Condition of Participation: Outpatient Services

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

Interpretive Guidelines §482.54

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

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

Tag 1080 provides more detailed guidance on the overall requirements for outpatient services and permits standard-level citations for identified deficiencies.

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

* * *

A-1079

(Rev.)

§482.54(b) Standard: Personnel

The hospital must --

- (1) Assign **one or more** individuals to be responsible for outpatient services.
- (2) Have appropriate professional and nonprofessional personnel available **at each location where outpatient services are offered, based on the scope and complexity of outpatient services.**

Interpretive Guidelines §482.54(b)

The hospital's outpatient services may be directed by one or more individuals. Hospitals have the flexibility to determine how best to organize their outpatient services, including how direction will be provided. As services offered in outpatient departments become more varied, complex and technologically advanced, hospitals may find it better to have individuals with more specialized expertise providing direction for a specific type of outpatient services.

Hospitals should define in writing the qualifications and competencies necessary for their outpatient services department leader(s). These qualifications should include items such as education, experience, and specialized training consistent with State law and acceptable standards of practice.

The hospital should define in writing the qualifications and competencies necessary to direct **each** outpatient service **for which there is a separate director**. Qualifications include necessary education, experience and specialized training consistent with State law and acceptable standards of practice.

Adequate types and numbers of qualified **licensed healthcare** professionals and **other** personnel must be available to provide patients with the appropriate level of care **for the outpatient** services offered by the hospital. The types and numbers of qualified personnel **required for area of the hospital's main campus or for each provider-based off-site location must be** based on the scope and complexity of **the** outpatient services offered and the number and types of patients treated as outpatients **at each**.

Survey Procedures 482.54(b)

- *Ask the hospital how it has organized its outpatient services and to identify the individual(s) responsible for providing direction for outpatient services.*
- Review the organization's policies and procedures to determine the person's responsibility.
- Review the position description and personnel file of the individual(s) responsible for *a selection of* outpatient services to ensure that *they are qualified*, in accordance with State law, acceptable standards of practice and hospital policy *to direct the service for which they are responsible.*
- *Visit several on- and off-campus locations where hospital outpatient services are provided. Given the scope and complexity of the services being offered, are there sufficient personnel with the appropriate education, experience, certifications, current licensure where appropriate, and competencies for assigned responsibilities?*

A-1080

Standard-level Tag for

§482.54 Condition of Participation: Outpatient Services

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

Interpretive Guidelines §482.54

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

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

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

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally

recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc).

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

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

The hospital's medical staff policy for authorizing practitioners to refer patients to the hospital with orders for specific outpatient services must address how the hospital verifies that the referring/ordering practitioner who is responsible for the patient's care is appropriately licensed and acting within his/her scope of practice. The policy must also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with medical staff privileges. For example, a hospital may prefer not to accept orders for a regimen of outpatient chemotherapy or outpatient therapeutic nuclear medicine services from a referring physician who does not hold medical staff privileges. In such cases, the hospital's policy must make these exceptions to the general authorization for accepting orders from referring practitioners clear.

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

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

Survey Procedures §482.54

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

- *Ask the individual(s) directing outpatient services whether the hospital orders for that type of outpatient service from referring physicians who are not members of the hospital's medical staff. If yes:*
 - *Ask for evidence that the medical staff has approved the policy.*
 - *Ask how the hospital verifies that the order comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she sees the patient to prescribe such orders. Ask for documentation of such verification efforts.*

State Operations Manual

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev.)

Transmittals for Appendix W

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C-0151

(Rev.)

§485.608(a) Standard: Compliance with Federal Laws and Regulations

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Interpretive Guidelines §485.608(a)

Each CAH must be in compliance with applicable Federal laws and regulations related to the health and safety of patients. This includes other Medicare regulations and Federal laws and regulations not specifically addressed in the CoPs. State Survey Agencies are expected to assess the CAH's compliance with the following Medicare provider agreement regulation provisions when surveying for compliance with §485.608(a):

Advance Directives

An advance directive is defined at 42 CFR 489.100 as “a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.” In accordance with the provisions of 42 CFR 489.102(a), the advance directives regulations apply to CAHs. The CAH patient (inpatient or outpatient) has the right to formulate advance directives, and to have CAH staff implement and comply with the individual's advance directive. The regulation at [42 CFR 489.102](#) specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives.

In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively, the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a “support person,” as specified in §485.635(f), for purposes of exercising the patient's visitation rights.) When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the CAH must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The

CAH must also seek the consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative in the patient's advance directive takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the CAH to:

- Provide written notice of its policies regarding the implementation of patients' rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the CAH may provide the advance directive information required under §489.100 to the individual's "family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law." (§489.102(e)) §489.102(b)(1) requires that notice of the CAH's advance directive policy be provided at the time an individual is admitted as an inpatient. However, the CAH should also consider providing the advance directive notice at the time of registration, to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery.
- The notice must include a clear and precise statement of limitation if the CAH cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:
 - Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners;
 - Identify the State legal authority permitting such an objection; and
 - Describe the range of medical conditions or procedures affected by the conscience objection.

It should be noted that this provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures. This provision would not allow a CAH or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient's representative and/or support person, given that such designation does not concern a medical condition or procedure.

Issuance of the written notice of the CAH's advance directive policies to the patient or the patient's representative must be documented in the patient's medical record.

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;

- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
- *Assure* compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;
- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and
- Provide community education regarding advance directives and the CAH must document its efforts.

A **psychiatric advance directive** is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the CAH, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. CAHs should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the CAH's professional staff as they develop a plan of care and treatment for the patient.

Required CAH Disclosures to Patients:

Physician Ownership

- [42 CFR 489.3](#) defines a "physician-owned hospital" as any participating hospital, including a CAH, in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the CAH, except for those satisfying an exception found at [§411.356\(a\) or \(b\)](#). *Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.*

- However, the notice requirement does not apply to any physician-owned CAH that does not have at least one referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the CAH or who has an immediate family member who has an ownership or investment interest in the CAH. In such cases, the CAH must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the CAH. The CAH must maintain this attestation in its records.
- 42 CFR 489.20(u)(1) requires that all physician-owned CAHs provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist the patient in making an informed decision about his or her care.
 - *A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.*
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the CAH must provide it at the time of the request.
- 42 CFR 489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the CAH their ownership or investment interest or that of any immediate family member in the CAH. The CAH must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital's policies and procedures governing privileges for physician owners.
 - The CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.
- [42 CFR 489.12](#) permits CMS to refuse to enter into a provider agreement with a physician-owned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).
- *[42 CFR 489.53\(c\)](#) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at [§489.20\(u\)](#).*

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that *if there is no doctor of medicine or osteopathy present in the CAH 24 hours per day, seven days per week the CAH must* provide written notice to all inpatients at the beginning of a *planned or unplanned* inpatient stay, *and to outpatients for certain types of* outpatient visits. *The purpose of the requirement is* to assist the patient in making an informed decision about his/her care. **CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24/7 do not need to issue any disclosure notice about emergency services capability.**

- *The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.*
- *The notice must be provided at the beginning of the planned or unplanned inpatient stay, or applicable outpatient visit.*
 - *A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.*
- *Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the CAH does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will meet the medical needs of any patient with an emergency medical condition, as defined in [42 CFR 489.24\(b\)](#) [the EMTALA definition], at a time when *there is no doctor of medicine or doctor of osteopathy present in the CAH. If an emergency department patient is determined to require admission, then the individual notice provisions of 42 CFR 489.20(w) would apply to that patient.**
- *Before admitting an inpatient or providing outpatient services requiring notice, the CAH must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to him/her.*
 - *In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.*
- *For a CAH that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and a separate remote location for a psychiatric or*

rehabilitation distinct part unit (DPU)) under one CMS Certification Number) *a separate determination is made for each campus/location with inpatient services as to whether the disclosure notice is required.* For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, *but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH's main campus does have an MD/DO present 24/7.*

- [42 CFR 489.53\(c\)](#) permits CMS to terminate a provider agreement with a CAH if the CAH fails to comply with the requirements at [§489.20\(w\)](#) when it does not have an MD or DO on-site 24/7.

Other Federal Requirements

Other Federal requirements also apply to patient health and safety in the CAH. For example, Federal laws and regulations govern both the disposal of medical waste and occupational health. However, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies and therefore do not assess compliance with non-CMS regulations. A surveyor who suspects a CAH may not be in compliance with other Federal requirements may refer the matter to the appropriate Federal agency. If CMS is notified or becomes aware of another Federal agency's final enforcement action, action will be taken only if the final enforcement action remains in effect.

Survey Procedures §485.608(a)

Assessing Compliance with Advance Directives Requirements

- Review the CAH's advance directive notice. Does it advise inpatients or applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have CAH staff comply with the advance directive (in accordance with State law)? Does it include a clear, precise, and valid statement of limitation if the CAH cannot implement an advance directive on the basis of conscience?
- Review the records of a sample of patients for evidence of CAH compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the CAH's advance directives policy was provided at the time of admission or registration? Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?
- What mechanism does the CAH have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the CAH is promoting and protecting each patient's right to formulate an advance directive?

- Determine to what extent the CAH complies, as permitted under State law, with patient advance directives that delegate decisions about the patient's care to a designated individual.
- Determine to what extent the CAH educates its staff regarding advance directives.
- Interview staff to determine their knowledge of the advance directives of the patients in their care.
- Determine to what extent the CAH provides education for the patient population regarding one's rights under State law to formulate advance directives.

Assessing Required Disclosures

Physician Ownership

- If the CAH indicates that it is physician-owned but is exempt *under §489.20(v)* from the disclosure requirement *of §489.20(u)(2)*, ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member has an ownership/investment interest in the CAH. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the CAH would not be cited.)
- If the CAH is physician-owned but not exempt from the *physician ownership* disclosure requirements:
 - Verify that appropriate policies and procedures are in place to *assure* that written notices are provided to all patients at the beginning of an inpatient or outpatient stay.
 - Review the notice the CAH issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the CAH meets the Federal definition of "physician-owned," that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such list is provided to the patient at the time the request is made by or on behalf of the patient.
 - Determine through staff interviews, observation, and a review of policies and procedures whether the CAH furnishes its list of physician owners and investors at the time a patient or patient's representative requests it.
 - Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned CAH's medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the CAH

agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at time of *the* referral to the CAH.

MD/DO 24/7 On-site Presence

- Determine through interviews, observation, and medical record review whether an MD/DO is present in the CAH 24 hours per day, 7 days per week. *For each required location where an MD/DO is not present:*
 - Verify that appropriate policies and procedures are in place to *assure* that written notices that a MD/DO is not present *at all times* are provided *at the beginning of a planned or unplanned inpatient stay or outpatient visit* to all *inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia*.
 - *Verify that there is a signed acknowledgement by the patient of such disclosure, obtained by the CAH prior to the patient's admission or before applicable outpatient services were provided.*
 - *Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the CAH.*
 - *Verify that the CAH's emergency department has signage with the appropriate disclosure information.*
 - Review the notice the CAH issues to verify that it indicates how the CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present *at that CAH, including any remote location*.

Other Federal Requirements

Surveyors do not assess compliance with Medicare payment provisions or non-Medicare requirements. However, a surveyor may refer suspected noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical and waste issues to EPA, blood-borne pathogens and TB control to OSHA, etc.).

* * *

C-0160

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent full survey. If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(d).

* * *

C-0165

(Rev.)

§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guidelines §485.610(c)

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination. *Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.*

* * *

C-0221

§485.623(a) Standard: Construction

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

Interpretive Guidelines §485.623(a)

The CAH's physical facilities must be constructed, designed and maintained such that patients are always accessible and the safety of patients is assured. The CAH's construction must be in accordance with applicable Federal, State and local law, as determined by the authorities having jurisdiction to enforce such law.

The CAH's physical plant must provide sufficient space to support those services the CAH provides on-site. There must also be adequate space to support all additional services the CAH offers.

Survey Procedures §485.623(a)

- Verify through observation that the physical facilities are large enough for the scope of services *the CAH is required to provide on-site, as well as any additional services it offers on-site or at a provider-based, off-site location. The adequacy of the space depends on both the nature of the services provided and the number of patients to whom the CAH typically provides those services.*
- Verify through observation that the CAH's building(s) is/are maintained in a manner to ensure the safety and well being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).
- Verify through observation that the design of the CAH assures that staff can reach patients readily.

* * *

C-0273

§485.635(a)(3) The policies include the following:

- (i) A description of the services the CAH furnishes, **including** those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH. For example, the CAH may contract with a laboratory to provide certain laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH. Note that there must be a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests and all laboratory services performed by the CAH. Every CAH laboratory must be operating under a current CLIA certificate appropriate to the level of services performed.

*The descriptions of the services provided may be brief but informative, for example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided), **radiologic tests and their interpretation**, **surgery** (with a list of the types of surgery available) would satisfy this requirement.*

Survey Procedures §485.635(a)(3)(i)

Verify that the CAH's healthcare policies identify and describe all healthcare services offered by the CAH, including services provided under arrangement or by agreement.

* * *

C-0281

§485.635(b) Standard: *Patient* Services

(1) General. The CAH **provides** those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity **hospital** outpatient department or emergency department. These **CAH** services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guidelines §485.635(b)(1)

This regulation addresses the minimum level of outpatient, services (with the exception of emergency services – see §485.635(b)(4)) which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement

or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician's office or in a hospital outpatient or emergency department that furnishes low intensity (i.e., less complex) services. Such services include, but are not limited to: taking a patient's medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients it services for basic ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner to come to the CAH to provide medical care.

Survey Procedures §485.635(b)(1)

- *Does the CAH provide on-site outpatient services that are typical of those provided in a physician office or low intensity hospital outpatient or emergency department, including medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?*
- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.
- Verify that the types and number of qualified personnel are appropriate for *the scope and complexity of the outpatient* services offered. Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.
- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

C-0282

§485.635(b)(2) Laboratory Services

The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public

Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones).**
- (ii) Hemoglobin or hematocrit.**
- (iii) Blood glucose.**
- (iv) Examination of stool specimens for occult blood.**
- (v) Pregnancy tests.**
- (vi) Primary culturing for transmittal to a certified laboratory.**

Interpretive Guidelines §485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

- Chemical examination of urine by stick or tablet method or both (including urine ketones);*
- Hemoglobin or hematocrit;*
- Blood glucose;*
- Examination of stool specimens for occult blood;*
- Pregnancy tests; and*
- Primary culturing for transmittal to a certified laboratory.*

These services may be provided by the by the CAH staff or under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency

needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH'S *emergency services* operations.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written *policies and procedures* for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).

Survey Procedures §485.635(b)(2)

- *Ask the CAH to identify which laboratory services it offers. Are the required lab services provided at the CAH's main campus?*
- *Does the CAH have a CLIA certificate or waiver, as applicable, for all laboratory tests performed in CAH facilities?*
- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
- *If the CAH refers specimens to another laboratory for testing, does the CAH have documentation that the referral laboratory is CLIA certified for the appropriate tests?*
- *Has the CAH identified laboratory services that must be available to support the emergency services the CAH provides? Ask the staff who furnish emergency services whether these laboratory services are available whenever they provide emergency services.*

C-0283

§485.635(b)(3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, such as ionizing radiation (radiography, computed tomography, fluoroscopy), which has enough energy to potentially cause damage to DNA, and other forms of radiation (ultrasound, magnetic resonance imaging) to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services *furnished by the CAH may* be provided by CAH staff *or under arrangement*. The CAH must maintain and have available diagnostic radiological services to *support the services the CAH provides to* meet the needs of *its* patients. These services must be available at all times *the CAH provides services, including emergency services*. The CAH *has the flexibility to choose the types and complexity of radiologic* services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, *Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology*, etc.

Qualified Radiologic Personnel

There should be written policies *that are* developed and approved by the *governing body or responsible individual and are* consistent with State law, *that* designate which personnel are qualified to use the radiological equipment, administer procedures, *and which studies require interpretation by a radiologist*.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer

radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

Information Only – Not Required/Not to be Cited

Well-designed radiologic services include a medical physicist, who, in conjunction with the person responsible for radiologic services, performs or supervises the pertinent procedures necessary to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. The responsibilities of the medical physicist include: protection of the patient and others from potentially harmful or excessive radiation; establishment of adequate protocols to ensure accurate patient dosimetry; the measurement and characterization of radiation; the determination of delivered dose; advancement of procedures necessary to ensure image quality; development and direction of quality assurance programs; and assistance to other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation (www.aapm.org). CAHs are encouraged to involve a medical physicist in the calibration of the imaging equipment and monitoring of radiation dosage exposures.

Safety from Radiation Hazards

The CAH must adopt *and implement* policies and procedures that *ensure* safety *from radiation hazards* for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least *the following*:

- Adequate radiation shielding for patients, personnel and facilities, *which includes*:
 - *Shielding built into the CAH's physical plant, as appropriate;*
 - *Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;*
 - *Types of containers to be used for various radioactive materials, if applicable, when stored, in transport, in use, and when disposed;*
 - *Clear Signage identifying hazardous radiation areas*
- *Clear signage identifying hazardous radiation areas;*
- Labeling of *all* radioactive materials, *including* waste, *with clear identification of all material(s)*;
- Transportation of radioactive materials between locations within the CAH;

- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- *Periodic testing of equipment for radiation hazards;*
- *Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;*
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. *The CAH must ensure that equipment is inspected in accordance with Federal and State laws and regulations, as applicable, and hospital policy.* The CAH must have a system in place to correct *identified problems*. The CAH must *have evidence of its inspections and corrective actions*.

Radiology Records

The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

Survey Procedures §485.635(b)(3)

- *Interview the person responsible for radiologic services.*
 - *Ask what radiologic services the CAH offers at its main campus. At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable.*
 - *Ask how the CAH ensures that radiologic services are provided consistent with acceptable standards of practice.*
- *Safety:*
 - *Determine if the radiologic services staff is familiar with the policies and procedures related to safety.*
 - *Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH.*
 - *Observe areas where radiologic testing is done and check for safety problems.*

- *Verify that hazardous materials are clearly labeled. Review records to verify that they are tracked, handled and stored properly in a safe manner with the requisite containers.*
- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
- *Equipment maintenance:*
 - *Review the inspection records to verify that periodic inspections are conducted.*
 - *Determine whether any problems identified are properly corrected in a timely manner and the correction is maintained over time.*
- *Qualified Personnel:*
 - *Are studies interpreted only by qualified staff approved to do so by the CAH's governing body or responsible individual?*
 - *Determine which staff are using various pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine if they meet the qualifications for tasks they perform, as established in the CAH's policies and consistent with state law.*
 - *Ask staff to explain the protocol for the procedures/studies they administer. Ask to see the CAH's written protocols and verify that the staff is adhering to them.*

C-0284

§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical **services** as a first response to common life-threatening injuries and acute illness.

Interpretive Guidelines §485.635(b)(4)

Emergency services must be provided by the CAH at the CAH campus either by CAH staff or under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide initial interventions, treatment and stabilization of any patient who requires emergency services.

Survey Procedures §485.635(b)(4)

Review policies and procedures for the provision of emergency services under §485.618.

* * *

C-0320

§485.639 Condition of Participation: Surgical Services.

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH provides surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, 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 *periOperative Registered Nurses*, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the CAH'S outpatient surgical services must be *integrated* with the *CAH's* inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the *governing body or responsible individual*.

Supervision in the OR

The operating room must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies.

If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures

Policies governing surgical care should contain:

- Aseptic surveillance and practice, including scrub techniques
- Identification of infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
 - Preoperative work-up
 - Patient consents and releases
 - Clinical procedures
 - Safety practices
 - Patient identification procedures
- Duties of scrub and circulating nurse
- Safety practices
- The requirement to conduct surgical counts in accordance with accepted standards of practice
- Scheduling of patients for surgery
- Personnel policies unique to the OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.

- Sterilization and disinfection procedures
- Acceptable operating room attire
- Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and

- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
 - Level of activity

- o Respirations
 - o Blood pressure
 - o Level of consciousness
 - o Patient color
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register

The register should include at least the following information:

- Patient's name
- Patient's CAH identification number
- Date of the operation
- Inclusive or total time of the operation
- Name of the surgeon and any assistant(s)
- Name of nursing personnel (scrub and circulating)
- Type of anesthesia used and name of person administering it
- Operation performed
- Pre and post-op diagnosis
- Age of patient

Operative Report

The operative report would include at least:

- Name and CAH identification number of the patient;
- Date and times of the surgery;

- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
 - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
 - The conformance to aseptic and sterile technique by all individuals in the surgical area;
 - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
 - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical *attire*, that surgical *attire is* designed for maximum skin and hair coverage;
 - That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and
 - 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.

- Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.
- If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.
- Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.
- Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.
- Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.
- Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.
- Check to determine that the operating room suite has available the items listed.
 - On-call system
 - Cardiac monitor
 - Resuscitator
 - Defibrillator
 - Aspirator (suction equipment)
 - Tracheotomy set (a cricothyroidotomy set is not a substitute)
- Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.
- Verify that the CAH has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room area.

- Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.
- Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

State Operations Manual

Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

(Rev.)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol

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§416.43(e) Standard: Governing Body Responsibilities

§416.44 Conditions for Coverage: Environment

§416.44(a) Standard: Physical Environment

§416.44(b) Standard: Safety From Fire

§416.44(c) Standard: Emergency Equipment

§416.44(d) Standard: Emergency Personnel

§416.45 Condition for Coverage: Medical Staff

§416.45(a) Standard: Membership and Clinical Privileges

§416.45(b) Standard: Reappraisals

§416.45(c) Standard: Other Practitioners

§416.46 Condition for Coverage: Nursing Service

§416.46(a) Standard: Organization and Staffing

§416.47 Condition for Coverage: Medical Records

§416.47(a) Standard: Organization

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

§416.48 Condition for Coverage: Pharmaceutical Services

§416.48(a) Standard: Administration of Drugs

§416.49 Condition for Coverage: Laboratory and Radiologic Services

§416.49(a) Standard: Laboratory Services

§416.49(b) Standard: Radiologic Services

§416.50 Condition: Patient Rights

§416.50(a) Standard: Notice of Rights

§416.50(b) Standard: *Disclosure of physician financial interest or ownership*

§416.50(c) Standard: Advance Directives

§416.50(d) Standard: Submission and Investigation of Grievances

§416.50(e) Standard: Exercise of Rights and Respect for Property and Person

§416.50(f) Standard: Privacy and Safety

§416.50(g) Standard: Confidentiality of Clinical Records

§416.51 Condition: Infection Control

§416.51(a) Standard: Sanitary Environment

§416.51(b) Standard: Infection Control Program

§416.52 Condition: Patient Admission, Assessment and Discharge

§416.52(a) Standard: Admission and Pre-surgical Assessment

§416.52(b) Standard: Post-surgical Assessment

§416.52(c) Standard: Discharge

Part I

Ambulatory Surgical Center Survey Protocol

Introduction

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

Ambulatory Surgical Centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive Medicare/Medicaid payment. The goal of an ambulatory surgical center (ASC) survey is to determine if the ASC is in compliance with the definition of an ASC, ASC general conditions and requirements, and the conditions for coverage (CfCs) at 42 CFR 416 Subparts A through C.

Certification of ASC compliance with the regulatory requirements is accomplished through observations, interviews, and document/record reviews. The survey process focuses on an ASC's delivery of patient care, including its organizational functions and processes for the provision of care. The ASC survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that patients receive safe, quality care, and services.

Regulatory and Policy References

- The Medicare definition of an ASC is found at 42 CFR 416.2 Subpart A.
- General conditions and requirements for Medicare-participating ASCs are found at 42 CFR 416 Subpart B
- The CfCs for ASCs are located at 42 CFR 416 Subpart C.
- Survey authority and compliance regulations can be found at 42 CFR 416 Subpart B and at 42 CFR Part 488 Subpart A.
- Should an individual or entity (ASC) refuse to allow immediate access upon reasonable request to either a State Agency (SA) or CMS surveyor, the Department of Health and Human Services Office of Inspector General (OIG) may exclude the ASC from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. If a surveyor intends to make a request for immediate access with the threat of possible exclusion for non-compliance, the SA must first contact the CMS Regional Office, which must then contact the OIG Administrative and Civil Remedies Branch at 202-619-1306.
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

All ASC surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Tasks in the Survey Protocol

The tasks included in a survey protocol for an ASC are:

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

Task 1 – Off-Site Preparation

General Objectives

The objectives of this task are to determine the size and composition of the survey team and to analyze information about the provider/supplier in order to identify areas of potential focus during the survey. Review of information about the ASC allows the SA (or RO for Federal teams) to develop a preliminary survey plan.

A full or standard survey will be conducted if the purpose of the survey is for initial certification, recertification, or validation of an accreditation organization survey. Surveys in response to a complaint or multiple complaints, or as a revisit to see if a previously cited problem has been corrected, will be focused on the CfCs related to the complaint or on the CfC for which deficiencies were previously identified. This does not preclude the scope of a complaint or revisit survey being expanded, if surveyors observe deficient practices related to other CfCs while on site. (See State Operations Manual, §§5100.1 and 5200.1.)

Types of Surveys

Standard or Full surveys: Initial certification, recertification, and representative sample validation surveys require assessment of the ASC's compliance with all Conditions for Coverage, including the Life Safety Code standards.

- Initial surveys are conducted when an ASC first seeks to participate in the Medicare program.
- Recertification surveys are required to reconfirm at periodic intervals the ASC's ongoing compliance.
- Representative sample validation surveys are conducted to support CMS' oversight of national accreditation organizations (AO) whose ASC programs have been recognized by CMS as suitable for deeming an accredited ASC as meeting the Medicare CfCs. CMS selects the ASCs for this type of validation survey, and the SA must complete its survey

no later than 60 days after the AO's survey. Although the primary purpose of the survey is to validate the AO's oversight, if substantial noncompliance is found by the SA and the RO concurs, the RO initiates appropriate enforcement action. SAs may only survey a deemed ASC when authorized to do so by the CMS Regional Office.

Complaint, Substantial Allegation Validation, or On-site Revisit Surveys: Generally, these types of survey are more narrowly focused than a full standard survey.

- A complaint is an allegation of noncompliance with Medicare health and safety standards. The purpose of a complaint survey is to determine the validity of the allegation and assess the current compliance of the ASC with those CfCs that are relevant to the substance of the allegation that triggered the survey.
- The purpose of the on-site revisit survey is to determine the ASC's current compliance with CfC requirements that the ASC was previously cited for noncompliance.
- The second type of validation survey is the substantial allegation validation. A complaint that alleges substantial noncompliance on the part of a deemed ASC with the Medicare health and safety standards may result in RO direction to the SA to conduct a substantial allegation validation survey. The SA uses the same methodology as for a complaint survey of a non-deemed ASC. The CMS Regional Office must authorize the State Survey Agency to conduct a substantial allegation validation survey and will specify the CfCs to be assessed.

Generally, complaints received by the SA or CMS concern specific cases or incidents that occurred in the past. However, CMS evaluates ASCs only for their current compliance or noncompliance at the time of the survey. Nevertheless, if an investigation of a complaint substantiates a violation in the past of one or more of the CfC requirements, and there is no evidence that the ASC subsequently implemented effective corrective action, then the findings substantiating the violation are documented on the Form CMS- 2567, Statement of Deficiencies and Plan of Correction as evidence of current noncompliance. On the other hand, if an allegation of a violation is substantiated, but the ASC subsequently implemented effective corrective action and the survey reveals no current noncompliant practices, then the ASC is in current compliance and is not cited for a deficiency based on the past noncompliance.

A revisit survey will focus on assessing the ASC's current compliance with the CfCs where deficiencies were cited on the previous survey. The SA must receive an acceptable plan of correction from the ASC before it conducts a revisit survey.

Survey Team Size and Composition

The SA (or the CMS RO for Federal teams) decides the composition and size of the team. In general, a survey team for a standard, i.e., full, survey should include two health standards surveyors and one Life Safety Code (LSC) surveyor, who are on-site for 2 days, but individual circumstances may call for a smaller or larger team, or a shorter or longer period of time on-site.

The following factors are considered when determining survey team size and the scheduled length of the survey:

- Size of the ASC, based on its number of operating or procedure rooms (ORs), hours of operation, and/or available information about its average monthly volume of cases;
- Complexity of services offered, e.g., a single type of surgical service, such as eye surgery, or multiple types, such as eye surgery, orthopedic surgery, endoscopies and gynecological procedures;
- Whether the ASC has an historical pattern of serious deficiencies or complaints; and
- Whether new surveyors are to accompany the team as part of their training.

For a complaint or on-site revisit survey, only one surveyor will usually be needed and should be chosen based on their knowledge of the CfC(s) that will be reviewed during the survey.

The ASC surveyors must have the necessary training and experience to conduct a survey. Completion of the Principles of Documentation Training Course is required. Completion of the Basic Ambulatory Surgery Survey Course is required for all health standards surveyors, unless such training has not been offered by CMS in the previous 2 years. All Life Safety Code (LSC) surveys must be conducted by surveyors who have completed the Basic LSC Surveyor Course. All ASC survey teams must include at least one RN with hospital or ASC survey experience who has the expertise needed to determine if the facility is in compliance with the Conditions for Coverage. New surveyors may accompany the team prior to completing the required training.

Team Coordinator

The SA (or the RO) usually designates a Team Coordinator when the survey team consists of more than one surveyor. The Team Coordinator will be responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol. Responsibilities of the Team Coordinator include:

- Acting as spokesperson to the ASC for the team;
- Conducting the entrance and exit conferences,
- Providing other on-going feedback, as appropriate, to ASC leadership on the status of the survey.
- Assigning team members specific survey tasks;
- Facilitating time management;

- Encouraging ongoing communication among team members;
- Evaluating team progress in completing the survey and coordinating team meetings; and
- Coordinating the preparation of the Form CMS-2567, Statement of Deficiencies and Plan of Correction, as well as all other reports/documentation required by CMS.

Assembling Background Information

Surveyors must prepare for the survey offsite, in order to make efficient use of the time onsite at the ASC. If the survey involves more than one surveyor, the Team Coordinator will arrange an offsite preparation meeting. If necessary, this meeting may be by conference call rather than in person. The type of background material to be gathered from the SA's files and/or CMS data bases includes:

- Basic characteristics of the ASC, including the facility's ownership, hours of operation, size, and types of surgical services offered. The most recent Form CMS-377 "Ambulatory Surgical Center Request for *Initial Certification or Update of Certification Information* in the Medicare Program", shows what the ASC indicates are the services it offers, but this form may be out of date. Other sources of information may include the SA's licensure file;
- Any additional information publicly available about the ASC, e.g., from its Web site, media reports, etc.;
- Any available information on the physical layout of the ASC;
- Whether any Life Safety Code waivers have been issued and are still in effect;
- Survey history and results of previous Federal and State surveys. In the case of a complaint survey, information on whether there were similar complaints investigated in the past; and
- Directions to the ASC.

During the meeting, the team discusses:

- Any significant information identified from the background information assembled;
- Whether there are CfCs requiring particular attention:

- In the case of a complaint survey, the SA or the RO (in the case of a deemed ASC) identifies in advance of the onsite investigation which CfCs will be surveyed for compliance;
- In the case of an on-site revisit survey, surveyors will focus on the ASC's current compliance with those CfCs where deficiencies were cited on the most recent Form CMS-2567. Surveyors also review the ASC's plan of correction and will look for evidence while onsite that the plan was implemented. (However, surveyors may not assume that implementation of the plan always means that the ASC is in substantial compliance with the CfC. It is possible that a plan of correction may be implemented, but is not sufficient to bring the ASC into compliance.);
- Preliminary team member assignments;
- Any questions the team has about how they will evaluate the CfCs;
- Date, location, and time team members will meet to enter the facility;
- When daily team meetings will take place if needed; and
- The anticipated date and time of the Exit Conference.

For surveys involving only one surveyor, that surveyor also needs to gather background information and plan the strategy for the survey prior to arriving on-site.

NOTE: Conduct ASC surveys during the ASC's normal business hours. All surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Resources

The following resources are useful to bring on surveys:

- Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers in the SOM;
- Appendix I – Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys in the SOM;
- Appendix Q - Immediate Jeopardy in the SOM;
- Several copies of the regulatory language at 42 CFR 1001.130 regarding the consequences of failure to permit the survey team access to the facility;
- For deemed accredited facilities, Exhibit 37, Model Letter Announcing Validation Survey of Accredited/Deemed Provider/Supplier, and Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey.

Task 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the ASC staff and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the ASC together. Upon arrival, surveyors must present their identification. If the ASC denies entrance to the facility or otherwise tries to limit required survey activities, explain the requirements under 42 CFR 1001.1301 and present a hard copy of the regulatory citation. Explain that failure of the ASC to allow access for an onsite survey could lead to exclusion of the ASC from Medicare.

If surveyors encounter any problems onsite, they should feel free to contact their SA manager or the RO for guidance. For instance, if ASC staff will not let a surveyor into the facility even after they're informed of the possible sanctions that can be imposed for restricting access to their facility, a call to the SA or RO would be appropriate.

Because the survey is unannounced, surveyors should anticipate that in some ASCs, e.g., a small ASC with one physician owner who performs all the ASC's procedures, the ASC's leadership may at the time of entrance by the survey team already be involved in a procedure and unavailable. If there would be a prolonged wait for the ASC's leadership, e.g., a wait exceeding 15 minutes, the team should conduct the entrance conference with available ASC senior staff; a separate brief discussion can be held at a later mutually convenient time with the ASC's leadership.

The Team Coordinator (or the single surveyor for complaint or revisit surveys) will announce to the ASC's Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or available, the Team Coordinator asks that *the Administrator or person in charge* be notified that a Federal survey is being conducted. Do not delay the survey because the Administrator is not available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Surveyors must be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief.

During the entrance conference, the Team Coordinator or single surveyor:

- Explains the purpose and scope of the survey (initial certification or recertification; complaint investigation; validation; revisit);

- In the case of a validation survey – either representative sample or substantial allegation (complaint) - of a deemed ASC, presents the letter explaining the survey and has the Administrator sign the authorization for the survey (Exhibit 287)
- Briefly describes the survey process;
- Introduces the survey team members, including any additional surveyors who may join the team at a later time, and discusses in general what the surveyors will do and the various documents they may request;
- Clarifies that all areas of the ASC, including the OR(s) or procedure rooms may be surveyed, but emphasizes that the survey team will not interfere with the provision of patient care and will take all standard precautions to avoid any infection control breaches; patients will be asked if they object to having their surgery observed;
- Explains that all interviews will be conducted privately with patients, staff, or visitors, unless requested otherwise by the interviewee;
- Discusses how the facility will provide the surveyors in a timely manner photocopies of material, records, and other information as needed;
- Obtains the names, locations, and telephone numbers of key ASC staff and their responsibilities;
- Discusses the appropriate time, location, and possible attendees of any meetings to be held during the survey; and
- Proposes a preliminary date and time for the exit conference.

During the entrance conference, the Team Coordinator arranges with the ASC Administrator or available administrative supervisory staff in his/her absence, to obtain the following:

- A list of all surgeries scheduled for that day (and the next if a 2-day survey); the list should include each patient's name, age, type of surgical procedure scheduled or performed, and the physician performing the procedure. The Team Coordinator indicates that one surveyor will be following the progression of at least one patient from initial registration through to discharge from the ASC (or at least through the initial period in the recovery room), so it is essential that information on these cases be provided as soon as possible, including the expected time between registration and discharge.
- A list of:

- All surgeries from the past 6 months. In the case of a complaint survey concerning a surgery that took place further in the past, be sure to request a list that includes the month of the complaint case; and
- All cases in the past year, if any, where the patient was transferred from the ASC to a hospital or where the patient died;

The list should include each patient's name, age, type of surgical procedure scheduled or performed, and the name of the physician performing the procedure. The Coordinator explains to the ASC that, in order to complete the survey within the allotted time, it is important the survey team is given this information as soon as possible. The ASC should begin compiling this list as soon as the entrance conference concludes. Generally an ASC should be able to provide this information within 1 to 2 hours of the request.

- A location (e.g., conference room, an office not in use) where the survey team may meet privately during the survey, and also conduct record reviews, interviews, etc.;
- A telephone, preferably in the team meeting location;
- A list including the names of the Director of Nursing, active Medical Staff, Allied Health professionals, and all other staff providing patient care;
- A copy of the facility's organizational chart;
- Selected ASC written policies and procedures;
- Selected ASC personnel records;
- Written documentation related to the ASC's infection control program and its program for ongoing self-assessment of quality;
- A list of contracted services; and
- A copy of the facility's floor plan.

For initial or recertification surveys, arrange an interview with the administrative staff member who will be providing information enabling the survey team to complete the Form CMS-377, Ambulatory Surgical Center Request for *Initial Certification or Update of Certification* in the Medicare Program. Note that for recertification surveys, the ASC's management is not required to sign this form, since certification is ongoing and there is no requirement for the ASC to request recertification.

Task 3 – Information Gathering/Investigation

General Objective

The objective of this task is to determine the ASC's compliance with the CfCs through observations, interviews, and document review.

During the Survey

- Surveyors should always maintain a professional and calm demeanor;
- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. However, maintaining open and ongoing dialogue with the facility staff throughout the survey process generally enhances the efficiency and effectiveness of the survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey;
- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey;
- Surveyors are not permitted to conduct clinical examinations or provide clinical services to any of the ASC's patients. Surveyors may direct the attention of the ASC staff to address an immediate and significant concern affecting a patient's care. All significant issues or significant adverse events, particularly those that a surveyor believes may constitute an immediate jeopardy, must also be brought to the Team Coordinator's attention immediately. Immediate jeopardy is defined as a situation in which the ASC's noncompliance with one or more CfCs has caused, or is likely to cause, serious injury, harm, impairment or death to a patient. If the Team Coordinator agrees that there is an immediate jeopardy situation, the team will follow the guidance in Appendix Q of the State Operations Manual.
- Informal conferences with facility staff may be held in order to inform them of preliminary survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues;
- The survey team should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, and areas of concern, as well as to identify areas for additional investigation. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues; and

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided to the ASC upon request, the surveyor is not a consultant and may not provide consulting services to the ASC.

Observations

Observations provide direct knowledge of the ASC's practices, which the surveyor must compare to the regulatory requirements in order to determine whether the ASC is in compliance with the requirements. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Case Observation

The Team Coordinator should make it a priority at the beginning of the survey to select one or more surgical cases scheduled for observation during the survey. To form a more accurate picture of the ASC's routine practices, it is preferable to observe a case on the first day of the survey. ASC patients remain in the ASC up to a maximum of 24 hours; therefore, following individual cases from start to recovery or discharge is an effective tool for assessing the ASC's compliance with the CfCs. The number of cases selected will depend on the size of the team, the scheduled length of the survey, and the expected duration of the surgical case. Depending on the timing of the case selected, a surveyor may begin a case observation immediately.

The surveyor could follow the patient from pre-operative preparation and assessment to discharge (but at least through post-anesthesia recovery). For larger ASCs, i.e., those with more than 2 ORs or procedure rooms, or for multi-specialty ASCs, surveyors should consider following two cases.

In selecting cases to follow, surveyors should choose more complex cases, based on the type of procedure or patient age or patient co-morbidities. It may also be useful to avoid selecting cases where surveyors anticipate that patient modesty concerns may make it harder to obtain the patient's consent. As a general practice, to make efficient use of onsite time, surveyors should not select cases where the operative time is expected to exceed 90 minutes. Surveyors may opt not to observe the whole surgery from start to finish; however, in such cases they must assure they are in the OR when the patient is brought in, in order to observe the start of the surgery, and they must return to the OR before the case concludes. It may be useful for a surveyor to remain in the OR after the patient leaves, in order to observe how the OR is cleaned and prepped for the next case. In such cases the team should arrange for another surveyor to pick up the observation of the patient's care after the first surveyor leaves the OR.

In following the case(s) surveyors will look for evidence of compliance related to the various CfC requirements, e.g., infection control, physical environment, medication administration, assessment of anesthesia and procedure risk as well as the required pre-operative update assessment of changes from the history and physical, provision of surgical and anesthesia services, post-surgical assessment, recovery from surgery and anesthesia, and discharge orders.

ASC Tour

The tour may be accomplished before case observation, or surveyors who are not following a case may tour the ASC while the ASC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole ASC and to begin making findings about its compliance with the Cf C governing an ASC's environment, 42 CFR 416.44. The amount of time spent on the tour will depend on the size of the ASC, e.g., the number of ORs/procedure rooms, recovery rooms, etc. For revisit surveys, a tour of the whole facility is generally not necessary.

Observation Methods

When making observations, surveyors attend to the following; specific areas or activities to observe are discussed in the guidance for each CfC requirement.

- Building structure and layout, general appearance of cleanliness, odors;
- Staff-patient interactions, both clinical and non-clinical. For example, what happens to patients from the time they arrive at the ASC until the time they leave? Are their privacy and other rights protected? Is care provided by appropriate, qualified staff? Is patient identity verified by each staff member before care is provided?; and
- Other staff activities. For example, how do staff protect the confidentiality of medical records? Are infection control precautions observed? Are staff aware of regulatory requirements pertinent to their activities?

A surveyor must take detailed notes of all observations, identifying the regulatory standard(s) to which the observations relate to. For example, one set of observations might support findings related to multiple standards, or some surveyors may find it convenient to use interpretive guidance "tag" numbers as a convenient shortcut for identifying the applicable standards. When such tags are used, the surveyor must always recall that tags are just a filing/sorting device, and that the regulatory authority is always based on the specific regulatory language. With the approval of the SA, surveyors should also feel free to use templates or worksheets that will help record their survey findings.

Surveyors must attempt to obtain verification of the factual accuracy of their observations by the patient, family, facility staff, other team member(s), or by another means, as appropriate. For example, when finding an outdated medication on the anesthesia cart, surveyors can ask the ASC staff member who has responsibility for anesthesia to verify the drug's expiration date.

Surveyors must first obtain the permission of the patient or the patient's representative in order to observe the delivery of care to that patient. The privacy and dignity of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to observe his/her care. For observation of a surgical case, the patient's consent to the surveyor's observation must be included/added to the patient's informed consent. It is at the surveyor's discretion whether he or

she prefers ASC staff to first approach a patient about the possible observation of his or her procedure, or whether the surveyor approaches the patient directly to seek permission. In all cases, the surveyor must speak directly with the patient to obtain consent.

The surveyor is not required to obtain the consent of the operating physician prior to observing a surgical procedure. The surveyor may observe any and all cases and activities upon request as needed in order to assess compliance with the Medicare ASC CfCs. An ASC may not condition a surveyor's ability to observe patient care by, for example, requiring a surveyor to sign any written documents or to present proof of vaccinations. The surveyor, however, must ensure that his/her observation protects patient safety and does not interfere with the operating physician or the surgical procedure.

If a facility denies a surveyor access to ASC activities which must be evaluated to determine compliance with the Medicare ASC CfCs, then the facility has failed to provide evidence of compliance and must be cited accordingly. In addition, the ASC may be subject to exclusion from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. See "Regulatory and Policy References" section in this Appendix.

For each observation, the surveyor should document:

- The date and time of the observation(s);
- Location within the ASC;
- Patient and staff identifiers. A key containing identifiable information for patients must be kept on a separate identifier list. The ASC/surveyor may not use medical record numbers, Social Security numbers, or billing record numbers to identify patients, or the names or position numbers to identify staff members;
- Individuals present during the observation;
- Activity/area being observed (e.g., observation of sterile technique in the operating room, operative instrument cleaning and sterilization, recovery room care, etc).

Use of Infection Control Tool

CMS has developed, with the assistance of the Centers for Disease Control and Prevention (CDC), a comprehensive survey tool to assist surveyors in evaluating the infection control practices of an ASC. The tool may be found at Exhibit 351 of the State Operations Manual. One surveyor must be assigned to complete this tool during the survey, but all surveyors should be alert to breaches of standard infection control practices and share such observations with the surveyor completing the tool. The tool utilizes a combination of direct observations and interviews in order to document the ASC's infection control practices.

Document Review

ASCs maintain a variety of documents that provide evidence of their compliance/non-compliance with the regulations. Review of documents is a key component of the survey; however, it is important to note that the review must always be supplemented by surveyor observations and interviews. In particular, it is never sufficient to determine compliance by merely verifying that an ASC has an appropriate written policy and procedure in place. Surveyors must use a variety of means, including review of other documents, such as patient medical records, personnel files, maintenance records, etc., to confirm that the ASC actually follows its policies and procedures in its daily operations. Documents reviewed may be both written and electronic and include the following:

- Medical records (see discussion below);
- Personnel files to determine if staff members have the appropriate educational requirements and training, and are licensed and credentialed, if required. The ASC must comply with all CMS requirements and State law as well as follow its own written policies for medical staff privileging and credentialing;
- Maintenance records to determine if equipment is periodically examined and to determine whether the equipment is in good working order and whether environmental and sanitary requirements have been met;
- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the ASC's leadership that the manuals are current; and
- Contracts and transfer agreements. Review to verify these are current.

Photocopies

Surveyors must photocopy all documents needed to support deficiency findings. The surveyor requires access to a photocopier in the ASC in order to make these photocopies. Generally surveyors must not rely upon ASC staff to make copies for them. However, if the ASC insists that one of its staff must operate the copier, then a surveyor must observe the copying process, in order to assure that changes or omissions do not occur. If requested by the ASC, the surveyor will make an extra copy of the photocopied items for the ASC's benefit. All photocopies must be dated and timed by the surveyor to reflect when they were photocopied. They must be properly identified, as appropriate, e.g., "ASC Recovery Room Policy – 10-25-07 or "Facility Surgical Instrument Sterilization Policy – 10-25-07, or "Patient #3 Preoperative Anesthesia Assessment - 10-25-07."

Medical Record Review

Closed Record Sample Size and Selection

After the ASC provides a log or some other record of closed cases from the past six months, the team/surveyor will select a sample of the medical records for these cases to review.

Sampling for Initial Surveys, Recertification Surveys, or Representative Sample Validation Surveys

For recertification and representative sample validation surveys, the sample selected must represent a cross section of the cases performed at the ASC (i.e., different surgical specialties, types of surgery, surgical cases using different types of anesthesia, different physicians, post-op infection, unplanned post-operative transfer, etc.) The sample must include Medicare beneficiaries as well as other patients. All deaths and transfers to hospitals should be included. At a minimum, the surveyor selects at least 20 records for a facility with a monthly case volume exceeding 50. For lower volume ASCs, the surveyor selects at least 10 records. The sample size may be expanded as needed in order to determine compliance with the ASC CfCs, at the Team Coordinator's discretion.

Initial survey closed record sample sizes should be chosen at the Team Coordinator's discretion, since the volume of closed cases may be small. The Team Coordinator determines if there are enough patients on the current surgical schedule and patient records (i.e., open and closed) for surveyors to determine whether the ASC can demonstrate compliance with all CfCs for each specialty performed in the ASC.

Sampling for Complaint Surveys

CMS always assesses an ASC for its current compliance with the CfCs. Thus, it is not sufficient to look only at the medical record for the complaint case in conducting a complaint investigation. The surveyor must determine whether at the time of the survey the ASC is in compliance with the CfCs selected for evaluation. If evidence of noncompliance is found to have occurred in the past and the systems and processes that led to the noncompliance remain unchanged at the time of the survey, this will be treated as continuing current noncompliance.

The RO (for deemed ASCs) or the SA (for non-deemed ASCs) will determine in advance of the survey which CfCs the surveyors will be evaluating in relation to the complaint. Selection of the CfCs will be determined based on the nature of the allegation(s) explicitly stated or implied by the complaint – i.e., an allegation of transmission of an infectious disease will require review of the infection control CfC, and probably also of the governing body CfC, while an allegation by a hospital that it received an emergency transfer of a patient who had suffered a surgical complication that called into question the safety and competence of the ASC would necessitate reviewing multiple CfCs, including surgical services, medical staff, and governing body, at a minimum.

It will be necessary to review several closed records. The selection of the sample to review will be dependent, in part, on the complaint allegations. Depending on the CfCs to be surveyed for a complaint, it may also be necessary to observe an open case. If the complaint concerns infection control, for example, following a case will provide a good opportunity to observe infection control practices throughout the ASC. On the other hand, if the complaint concerns a failure to

assess patients preoperatively for risk, it would be more appropriate to look at a sample of closed records for the documentation of the assessments, as well as to observe portions of several open cases, as the patients move from registration into the OR or procedure room, to observe the pre-operative assessments.

A revisit survey may or may not require review of open or closed cases, depending on the specific standards and conditions being re-evaluated.

The surveyor must assign a unique identifier to each patient case observed/reviewed during the survey. A key containing identifiable information for patients must be kept on a separate identifier list. Do not use medical record numbers, Social Security numbers, or billing record numbers to identify the patients or names or positions for staff.

Once the medical records are available, surveyors can begin reviewing each record for evidence of compliance/noncompliance. The interpretive guidelines for the specific regulatory standards can be used if that is their primary assignment.

In reviewing the record surveyors should confirm whether it contains items required by various CfCs, including but not limited to:

- A comprehensive medical history and physical assessment completed not more than 30 days before the date of the surgery;
- Pre-surgical assessments – update of the H&P upon admission, and assessment for the risk of the procedure and anesthesia;
- Documentation of properly executed informed patient consent;
- Findings and techniques of the operation, including complications, allergies or adverse drug reactions that occurred;
- Orders signed by the physician for all drugs and biologicals administered to the patient;
- Documentation of adverse drug reactions, if any;
- Documentation of the post-surgical assessment of the patient, including for recovery from anesthesia;
- Documentation of reason for transfer to a hospital, if applicable;
- Discharge notes, including documentation of post-surgical needs; and
- Discharge order, signed by the operating physician.

Interviews

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record review and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews:

- Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.
- Interviews with facility staff should be brief and to the point.
- Interviews should be used to determine whether staff is aware of and understand what they need to do for the ASC to comply with regulatory requirements, as well as the ASC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that allows surveyors to determine compliance with the regulations.
- Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.
- Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of building emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this ASC have policies and procedures to address emergencies?" Likewise, ask, "Can you describe what typically happens in the OR before surgery begins?" Do not ask, "Does this ASC employ a standard 'time-out' procedure before beginning surgery?"
- Surveyors must always introduce themselves and ask patients or their representatives for permission to interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient in recovery appears to still be feeling the effects of the anesthesia, an interview request should not be made. The same holds if a patient appears to be experiencing significant pain or anxiety. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.
- Patient interview questions should focus on factual matters about which the patient is likely to have information. For example, ask "Did the doctor discuss your surgery with you today? What information did the doctor discuss with you about the surgery?" "Did you notice whether people washed their hands or used a cleaning gel before providing care to you?"
- Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to validate the patient's perception, or to gather additional information.
- Validate as much of the information collected via interviews as possible by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.

- If necessary, telephone interviews may be conducted for closed cases; however, in-person interviews are preferred.

Task 4 – Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews. The team's or surveyor's preliminary decision-making and analysis of findings assist in preparing the exit conference report.

Preparation

Prior to beginning this task, each surveyor must review his/her notes and completed worksheets related to observations and interviews, as well as the documents he/she has photocopied. The surveyor must be confident that he/she has everything needed to support his/her presentation of findings to the team, and to the SA manager when preparing a formal survey report.

Discussion Meeting

At this meeting, the surveyors share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. For initial, recertification, and validation surveys, the Team should proceed sequentially through the regulatory requirements for each CfC; for complaint surveys they should proceed to review each CfC selected for investigation. The team must reach a consensus on all findings of noncompliance. Decisions about deficiencies must be team decisions, with each member having input. The team must document the evidence that supports each finding of noncompliance. Any additional documentation or evidence needed to support identified noncompliance must be gathered prior to exiting the facility.

All noted noncompliance must be cited as a deficiency, even when corrected onsite during the survey.

When a noncompliant practice is determined to have taken place prior to the survey, this would be considered evidence of current non-compliance, **unless** there is documentation that the ASC identified the problem prior to the survey and implemented effective corrective action. In evaluating whether the ASC is currently in compliance, the survey team must consider:

- What corrective action the facility implemented;
- Whether the corrective action was sufficient to address the underlying, systemic causes of the deficiency;

- Whether the corrective action was evaluated for its effectiveness to sustain long-term compliance; and
- Whether there are any other findings from the survey indicating current non-compliance.

If the deficient practice is identified and corrected by the ASC prior to the survey and there is no other evidence of current non-compliance, do not cite noncompliance.

In the case of a revisit survey, the surveyor's task is to determine current compliance with the regulatory requirements that were cited during the previous survey and ensure that the implementation of the written plan of correction submitted by the ASC and accepted by the SA was effective in maintaining long term compliance. The surveyor should conduct observations, document reviews and interviews to confirm current compliance with the CfC(s) addressed by the plan of correction.

Integrating Findings

The survey team integrates the findings derived from document review, observations, and interviews that pertain to each CfC surveyed, in order to make a determination of whether there is evidence of compliance/non-compliance.

Determining the Citation Level of Deficiencies

Citing noncompliance at the appropriate level, i.e., standard- or condition-level, is critical to the integrity of the survey process.

The regulations at 42 CFR 488.26 state, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the Conditions for Coverage is noted, the determination of whether the lack of compliance is at the Standard or Condition level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients - and extent of noncompliance – i.e., is there noncompliance with the CfC stem statement, or how many different regulatory requirements within a CfC are being cited for noncompliance, or how frequent was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance. Likewise, when an ASC has multiple standard-level deficiencies in a CfC, this may add up to pervasive non-compliance and could be sufficient to find condition-level noncompliance.

Determinations of citation level for complaint surveys follow the same process that is applied to full surveys; the only difference is that the complaint survey itself is generally limited to the CfCs implicated in the complaint.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the Team Coordinator determines the best way to gather such information.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the ASC management of the team's preliminary findings.

Prior to the Exit Conference

- The Team Coordinator is responsible for organizing the exit conference, including who will have a speaking role.
- The health and Life Safety Code (LSC) surveyors/survey teams must have one joint exit conference if they are exiting at the same time; otherwise they may conduct separate exit conferences.
- If the team feels it may encounter a problem during the exit conference, the Team Coordinator should contact the SA manager in advance to discuss the potential problems and appropriate methods to handle them.

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys. However, there are some comparatively rare situations that justify refusal to conduct or continue an exit conference. For example:

- If the ASC is represented by an attorney (all participants in the exit conference, both surveyor team members and ASC staff, must identify themselves prior to beginning the exit conference), surveyors may refuse to conduct the conference if the attorney attempts to turn it into an evidentiary hearing; or
- If the ASC staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the SA for further direction.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA. Videotaping is also permitted, if the survey team agrees to this, and a copy is provided at the conclusion of the conference. The

survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

General Principles

The following general principles apply when conducting an exit conference:

- The ASC management determines which ASC staff will attend the exit conference;
- The identity of individual patients or staff members must not be revealed by the survey team when discussing the survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference or characterization by which identity may be deduced; and
- Because of the information gathering activities the survey team has already engaged in, in most instances members of the ASC's staff should generally be aware prior to the exit conference of the areas, if any, where the survey team has concerns. Accordingly, there should be few cases where the ASC has not already had the opportunity prior to the exit conference to present additional information that might be relevant to the survey team's findings. The exit conference is not the correct setting for further information-gathering activities.

Exit Conference Sequence of Events

Introductory Remarks:

- Thank everyone for their cooperation during the survey;
- Reintroduce all surveyors who participated in the survey, even if they are no longer in the facility;
- Briefly reiterate what was the reason for the survey (i.e., initial, recertification, validation, or complaint); and
- Explain how the team will conduct the exit conference and any ground rules:
 - The exit conference is an informal meeting for surveyors to summarize their preliminary findings;
 - Brief comments on the findings may be made by the ASC, but will not be debated; and
 - Whether comments will be permitted in the middle of a surveyor's presentation or only after the presentation has concluded.

Presentation of Findings

- Do not refer to any specific ASPEN software data tag numbers when describing deficiency findings. In the process of writing up the findings the SA will finalize just which tags/regulatory text to cite for each finding, so it would be premature to make such statements during the exit conference.
- Present the findings of noncompliance, explaining why the findings indicate noncompliance with the regulatory requirement. If the ASC asks for the pertinent regulatory reference, provide the citation for the applicable CfC.
- Do not make any general characterizations about the survey results (e.g., “Overall the facility is very good.” or “In general the facility is in compliance with Medicare requirements.”) Stick to presenting the specific factual findings.
- Do not make any statements about whether the findings represent condition-level or standard-level deficiencies. Avoid statements such as, “the condition was not met” or “the standard was not met.” It is better to state “the requirement related to XXX is not met.”
- If an immediate jeopardy situation was identified during the team discussion that the team had not previously discussed with the ASC’s management, explain the significance and need for immediate correction. Follow instructions in Appendix Q, Guidelines for Determining Immediate Jeopardy.
- Do not rank findings. Treat requirements as equal as possible.
- Be certain that all deficiency findings are discussed at the exit conference.

Closure

- Indicate the official survey findings are presented in writing to the ASC via the Form CMS-2567, Statement of Deficiencies and Plan of Correction, which will be prepared and mailed to the ASC within 10 working days. It documents either that no deficiencies were found, or the specific deficiencies found, relating each to the applicable regulatory requirement. There will also be a letter communicating whether or not CMS will be taking enforcement action as a result of the survey’s findings.
- The ASC’s plan of correction (POC) and time frames for implementation of corrective actions are incorporated into the Form CMS-2567 and returned to the SA. Explain that the Form CMS-2567 is the document disclosed to the public about the facility’s deficiencies and what is being done to remedy those (Form CMS-2567 with POC). The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey.

- If any deficiencies have been identified, inform the ASC that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.
- Explain that, if a POC is required, the ASC will have the following three options:
 - Accept the deficiencies stated on Form CMS-2567 and submit a PoC;
 - Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or
 - Record objections to cited deficiencies on Form CMS-2567, do not submit a PoC, but submit written arguments and documented evidence that the deficiencies are invalid.
 - CMS will consider objections and accompanying documentation that attempt to refute the factual accuracy of the survey findings, but will not entertain objections to CMS's judgment of the level, extent, scope or severity of a deficiency. CMS reviews additional documentation submitted by provider making an objection and, if the added evidence is convincing, will remove the deficiency.
 - If CMS disagrees with the ASC's objections, the ASC must submit an acceptable POC. Failure to submit an acceptable PoC or failure to correct a deficiency may result in termination of the ASC's supplier agreement in accordance with 42 CFR 488.28(a), and 416.35(b).

Explain that an acceptable plan of correction must contain the following:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The procedure for implementing the corrective actions;
- A completion date for correction of each deficiency cited;
- Monitoring and tracking procedures to ensure the POC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- *The* title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on Page 1 of the Form CMS-2567.

Indicate that the POC will be reviewed by the SA, or in some cases, the RO, to determine whether it is acceptable. If a POC is determined not to be acceptable, it will be returned to the ASC for revision.

State that in some cases, the SA will make an unannounced revisit survey to determine whether the ASC has come into compliance.

If the exit conference was audio- or videotaped, obtain a copy of the tape before exiting the facility.

All team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the team coordinator determines the best way to review the additional information. It is usually prudent for at least two individuals to remain if all of the team members do not leave at the same time.

Task 6 – Post Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and RO must follow the instructions in the SOM including:

- Timelines for completing each step of the process;
- Responsibilities for completing the Form CMS 2567, “Statement of Deficiencies,” following the “Principles of Documentation;”
- Notification to the ASC regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the RO for further action/direction, such as concurrence with findings for deemed ASCs, authorization of a full survey for deemed ASCs with condition-level deficiencies); and
- Compilation of documents for the supplier’s file.

Survey Package

The Team Coordinator will assign responsibilities for completion of the various elements of the survey package.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the ASC will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public on request.

Indicate on Form CMS-2567 whether any deficiency constitutes immediate jeopardy to the individual's health and safety.

Write each deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand what regulatory requirements were not met. The consequence for incorrectly or unclearly documenting deficiencies can be the inability of CMS to take needed enforcement action.

Refrain from making clinical judgments. Instead, focus on the ASC's policies and procedures, as well as how they were or were not implemented by the ASC's medical and other staff.

After you complete Form CMS-2567 in ASPEN, submit it to your supervisor for review. If, after reviewing the form, your supervisor approves what you have documented, you will begin working on the remainder of the survey package. If your supervisor does not approve the form, then you will make any requested changes.

Other Survey Package Documentation

Complete the following documentation in hard copy. For complaint investigations, attach these materials to the corresponding complaint in the Aspen Complaint Tracking System:

- Description of sample selection;
- Summary listing of sample cases;
- Summary of interviews;
- Complaint investigation narrative;
- Form CMS-378E Ambulatory Surgical Center Crucial Data Extract
- For all surveys with a Life Safety Code component, Form CMS-2786U Fire Safety Survey Report; and
- Form CMS-670, Survey Team Composition and Workload Report

General Provisions and Definitions; General Conditions and Requirements

Interpretive Guidelines

Q-0002

(Rev.)

§416.2 Definitions

As used in this part:

Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in Subpart B and C of this part.

Interpretive Guidelines: §416.2

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

- Is a distinct entity;
- 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;
- Has an agreement with Medicare to participate as an ASC; and
- 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:

- **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.

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.

- **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.

- **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.

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.

- 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 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.

- 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.

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 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: §416.2

- 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.
- 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.
- 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.
 - If an ASC complies with all other elements of the ASC definition but has permitted concurrent use by an adjacent physician's 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.
- 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.
 - 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.
 - 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.
 - 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.

- 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.
- 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.*
- Determine whether the medical records note the patient's admission and discharge time.
- Observe whether the ASC correctly notes the time of admission for patients checking in and being discharged.
- 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_F_C_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.

* * *

Q-0080

(Rev.)

§416.43 Condition for Coverage: Quality Assessment and Performance Improvement

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

Interpretive Guidelines: §416.43

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 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:

- 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.
- 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: §416.43

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

Q-0104

(Rev.)

§416.44(b) Standard: Safety From Fire

- (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Healthcare Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal/register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.**
- (2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.**
- (3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.**
- (4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.**
- (5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if-**

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

- (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;**
- (iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and**
- (iv) The dispensers are installed in accordance with the following provisions:**
 - (A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);**
 - (B) The maximum individual dispenser fluid capacity shall be:**
 - (1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.**
 - (2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;**
 - (C) The dispensers shall have a minimum horizontal spacing of 4 feet (1.2m) from each other;**
 - (D) Not more than an aggregate of 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;**
 - (E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;**
 - (F) The dispensers shall not be installed over or directly adjacent to an ignition source;**
 - (G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and**
- (v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.**

Interpretive Guidelines: §416.44(b)

Because ASCs are not permitted to provide care to patients exceeding 24 hours, they are, for purposes of compliance with National Fire Protection Association (NFPA) Life Safety Code (LSC) requirements, subject to a combination of healthcare and business occupancy

requirements. They are, therefore, unlike hospitals and other facilities that keep patients more than 24 hours, which are considered healthcare occupancies.

Compliance with LSC requirements for an ASC is assessed by a surveyor trained in the application of NFPA LSC standards.

The provisions of the NFPA LSC (2000 edition), Chapter 20, New Ambulatory Health Care Occupancies, apply as of January 10, 2003, the date when CMS adopted the NFPA 2000 edition for ASCs, to any new buildings used for an ASC, alterations to existing ASCs, and alterations to existing buildings for new occupation by an ASC. The chapter includes: general requirements regarding structure and applicability; means of egress requirements; requirements related to protection from hazards, alarms and other emergency requirements, and subdivision of space; building services; and operating features. For older ASCs that have not undergone renovations, the provisions of chapter 21, Existing Ambulatory Health Care Occupancies apply.

Emergency Power

The NFPA 2000 LSC requires that when general anesthesia or life support equipment is used, the ambulatory health care facility (ambulatory surgical center) shall be provided with an essential electrical system in accordance with NFPA 99, Health Care Facilities, 1999 edition. For ASCs newly constructed or renovated after January 10, 2003, a Type 1 essential electrical system shall be installed which may include a generator as the source of back-up electrical power. Existing ASCs may continue to use a Type 3 electrical system and may continue to use batteries as the source of back-up electrical power. Existing ASCs that change procedures that include the use of general anesthesia or life support equipment not previously required will be required to upgrade *their* existing electrical system to a Type 1 system including a generator back-up electrical source of power. In all cases, ASCs are expected to have a reliable source of back-up power that enables them to protect patients and staff when power is lost, including proceeding with the surgical procedure until such point as it is safe to either terminate or complete it.

Use of Alcohol-based Skin Preparations

See the interpretive guidelines for §416.42 related to use of alcohol-based skin preparations in anesthetizing locations. 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 by:

- 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;
- Ensuring that the alcohol-based skin prep solutions do 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;

- 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;
- 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 preoperative “time out” to minimize the risk of medical errors during the procedure such as verifying that the patient is receiving the correct surgery.

Failure to take these measures to reduce the risk of surgical fire when an alcohol-based skin preparation is used must be cited as a condition-level violation of §416.44.

State Code in Lieu of LSC

The process by which CMS reviews a State’s request to use of its State Code in lieu of the NFPA LSC is addressed in Survey and Certification policy memorandum S&C-08-34, September 5, 2008. CMS will advise any SA when and if it approves a State application to use the State Code in lieu of the LSC.

Survey Procedures: §416.44(b)

- States vary as to the type of personnel who conduct surveys for compliance with LSC requirements. Some States use fire authority personnel, while others use architects, engineers, or healthcare professionals with LSC training. In all cases, however, the surveyors must have training in the application of the NFPA’s LSC Standards to ASCs and must follow the guidance in Appendix I.
- Health surveyors observing ASC surgical case(s) should determine whether the ASC employs appropriate measures to reduce the risk of surgical fire when alcohol-based skin preparations are used.

Q-0105

(Rev.)

§416.44(c) Standard: Emergency Equipment

The ASC medical staff 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.

Interpretive Guidelines §416.44(c)

The ASC's medical staff and governing body must adopt written policies and procedures that address the specific types of emergency equipment that must be available for use in the ASC's operating room. No specific list of emergency equipment is specified in the rule, but the ASC is expected to maintain a comprehensive, current and appropriate set of emergency equipment, supplies and medications that meet current standards of practice and are necessary to respond to a patient emergency in the ASC.

The ASC must conduct periodic assessments of its policies and procedures in order to anticipate the emergency equipment, supplies and medications that may be needed to address any likely emergencies, taking into consideration the types of patients the ASC serves and the types of procedures performed in the ASC.

The ASC must provide the appropriate emergency equipment and supplies and qualified personnel necessary to meet the emergency needs of the ASC's entire patient population in accordance with acceptable standards of practice in the ASC industry. Acceptable standards of practice include adhering to State laws as well as standards or guidelines issued by nationally recognized professional organizations, etc. The ASC's policies and procedures must be written and ensure the emergency equipment is immediately available for use during emergency situations; be appropriate for the facility's patient population; and be maintained by appropriate personnel.

Immediately available for use

The ASC must have an adequate supply of emergency equipment and supplies immediately available to the operating room(s) (OR). The equipment and supplies must be in working condition. The ASC's policies must address whether the equipment and supplies must be present in each OR, or in what quantity and locations they will be available to all ORs as needed. In the case of an ASC with more than one OR, the medical staff should adopt a policy, in writing, that addresses:

- The type and quantity of emergency equipment and supplies that must be present in each OR; and*
- For equipment not present in each OR, how many items must be available and in which locations so that the equipment is immediately available when needed in each OR.*

The ASC must have qualified personnel capable of using all emergency equipment as necessary. Personnel must be able to utilize the emergency equipment in accordance with their scope of practice. There is no requirement for all ASC clinical personnel to be able to use all emergency equipment; however, whenever there is a patient in the OR, there must always be staff present capable of using the emergency equipment.

Although the regulation addresses availability of emergency equipment to the OR specifically, a prudent ASC should also make emergency equipment, supplies and medications available for patients in the recovery room.

Appropriate for the ASC's patient population

The policies and procedures must incorporate the emergency equipment, supplies, and medications that are most suitable for the potential emergencies associated with the procedures performed in the ASC and the population the ASC serves. The ASC's policies must take into account the ASC's patient population, particularly, any risks or co-morbidities prevalent among that patient population. The ASC must consider the types of procedures performed as well as the risks and types of emergencies that the ASC may face based on those types of procedures. For example, if an ASC routinely provides care to pediatric patients, it must ensure that it has equipment and supplies that are the appropriate size for pediatric patients.

The ASC would also need to take into account the types of anesthesia used for the procedures performed. It would be expected that an ASC using general anesthesia is doing more complicated procedures that may have a higher risk of emergent complications, in addition to the risks associated with the use of general anesthesia. The ASC would be expected to have a more extensive supply of emergency equipment, supplies and medications than an ASC which only uses local anesthesia to perform low-risk procedures. For example, if an ASC uses anesthetics that carry a risk for malignant hyperthermia, then the ASC is expected to have supplies of medications required to treat this emergency condition. The amount of medication that must be immediately available is to be based on available information on the frequency with which malignant hyperthermia may occur, as well as ASC patient characteristics, since the dosage for the emergency medication is weight-based. An ASC that performs bariatric procedures on obese patients would need to have more emergency medications available than would an ASC that specializes in pediatric procedures.

Maintained by appropriate personnel

The ASC must ensure that mechanical and electrical equipment must be regularly inspected, tested, and maintained to assure their availability when needed. Emergency supplies and medications must be regularly monitored and replaced when they are removed for use or expire. The ASC must use qualified personnel to maintain emergency equipment, supplies and medications. The ASC may use contracted personnel to perform these functions.

Survey Procedures: §416.44(c)

- *Ask to see the ASC's policies and procedures on emergency equipment and supplies. Has the ASC identified supplies and equipment that are likely to be needed in emergency situations?*

- *Ask the ASC how it determined that the specified emergency equipment, supplies and medications meet the emergency needs of the ASC's patients, taking into account the patient population and types of procedures performed and anesthesia used.*
- *For ASCs with multiple ORs, does the policy clearly identify the quantity of equipment, supplies and medications required and their location?*
- *Determine whether the designated emergency equipment is immediately available to the OR(s) if needed.*
- *Interview ASC clinical staff to determine if they know where the emergency equipment is located.*
- *Verify that there are sufficient clinical personnel qualified to utilize the emergency equipment, medications and supplies.*
- *Ask the ASC how it would handle simultaneous emergencies, e.g., an emergency in more than one OR, or an emergency in the OR and another one in the recovery room.*
- *Is there evidence that mechanical or electrical equipment is regularly inspected, tested, and maintained by qualified personnel?*
- *Are emergency supplies and medications current or expired?*

Q-0122

(Rev.)

§416.45(b) Standard: Reappraisals

Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

Interpretive Guidelines: §416.45(b)

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

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

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

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

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

The ASC should also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule, for example, any instance of gross misconduct by the practitioner.

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

Survey Procedures: §416.45(b)

- Does the **ASC** periodically reappraise all practitioners granted clinical privileges?
 - Ask the ASC's leadership how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?
 - Review the personnel records for all practitioners with privileges to practice in the ASC to determine whether they have been reappraised within the timeframe specific in the medical staff policy.
 - Do the reappraisals include evidence that data on the practitioner's practice within the ASC is considered along with the practitioner's credentials?
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Q-0160

(Rev.)

§416.47 Condition for Coverage: Medical Records

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

Interpretive Guidelines: §416.47

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(g), the ASC must ensure the confidentiality of each patient's medical record.

Survey Procedures: §416.47

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.

Q-0162

(Rev.)

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

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

- (1) Patient identification;**
- (2) Significant medical history and results of physical examination;**
- (3) Pre-operative diagnostic studies (entered before surgery), if performed;**
- (4) Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;**
- (5) Any allergies and abnormal drug reactions;**

- (6) Entries related to anesthesia administration;**
- (7) Documentation of properly executed informed patient consent; and**
- (8) Discharge diagnosis.**

Interpretive Guidelines: §416.47(b)

The medical record must contain all of the required elements listed in the regulation.

Specifically:

- The identity of the patient must be clear through use of identifiers such as name, date of birth, social security number, etc.
- A comprehensive medical history and physical assessment (H&P), completed and entered into the medical record in accordance with the requirements at §416.52, as well as the results of the pre-surgical assessments specified at §416.42 and §416.52.
- If pre-operative diagnostic studies were performed, they must be included in the medical record prior to the start of surgery.
- An operative report that describes the surgical techniques and findings. A pathologist's report on all tissues removed during surgery must also be included, unless the governing body has adopted a written policy exempting certain types of removed tissue from this requirement. Depending on the type of surgery performed in the ASC, tissue may or may not routinely be removed during surgery; no pathologist's report is required when no tissue has been removed. The governing body's policy on exemption should provide the clinical rationale supporting the exemption decision. For example, an ASC that performs cataract removal and implantation of an artificial lens might exempt from the pathologist's report requirement the ocular lens removed in routine procedures where there is no indication suggesting the presence of other disease for which a pathology analysis should be required. On the other hand, it generally would not be reasonable to exempt intestinal polyps removed during a colonoscopy, since a pathologist's analysis of the tissue would be required to confirm whether or not the polyp(s) were malignant growths.
- The patient's history of allergies or abnormal drug reactions prior to the surgery, as well as any allergies or abnormal drug reactions that occurred during or after the surgery prior to discharge.
- Information related to the administration of anesthesia during the procedure and the patient's recovery from anesthesia after the procedure.

- Documentation of a properly executed informed patient consent. A well-designed informed consent process would most likely include a discussion of the following elements:
 - A description of the proposed surgery, including the anesthesia to be used;
 - The indications for the proposed surgery;
 - Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity;
 - Treatment alternatives, including the attendant material risks and benefits;
 - Who will conduct the surgical intervention and administer the anesthesia;
 - Whether physicians other than the operating practitioner will be performing important tasks related to the surgery. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines; and
 - 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](#).
- Documentation of the patient's discharge diagnosis. The record should also include the patient's disposition, i.e., whether the patient was discharged to home (including to a nursing home for patients already resident in a nursing home at the time of surgery), or transfer to another healthcare facility, including emergent transfers to a hospital.

Survey Procedures: §416.47(b)

- Evaluate the sample of open and closed records selected for review to determine whether they contain all of the required elements. For open records of patients whose surgery has not yet begun, focus on the elements that must be present before surgery, e.g., H&P, immediate pre-surgical assessment, informed consent, etc. The absence of any required element must be cited as standard-level noncompliance. The absence of a number of elements from a number of medical records might warrant citation of condition-level noncompliance. Likewise the absence of one element from a number of medical records – e.g., lack of informed consent to surgery – should warrant citation of condition-level noncompliance.

- Ask the ASC's leadership if the ASC removes tissue during surgery and, if so, does it exempt any or all classes of tissue removed from the requirement for analysis by a pathologist? If yes, ask to see the policy and its rationale, to determine whether it was adopted by the governing body and whether the clinical rationale for the exemption is reasonable.
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Q-0219

(Rev.)

§416.50 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 Guidelines: §416.50

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 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: §416.50

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.

- 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.*
- 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.*
- 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.*

Q-0220 (Rev.)

§416.50.... 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 Guidelines: §416.50 (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: §416.50(standard-level citation only)

- *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 used by every ASC patient. Deficiencies related to posting of the notice are to be cited using tag -Q0219.*

Q-0221

(Rev.)

§416.50(a) Standard: Notice of Rights

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

Interpretive Guidelines: §416.50(a)

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

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

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

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

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

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: <http://www.medicare.gov/ombudsman/resources.asp>. Patients who are Medicare beneficiaries, or their representative or surrogates, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

The notice must:

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

Survey Procedures: §416.50(a)

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

Q-0223

(Rev.)

§416.50(b) Standard: Disclosure of physician financial interest or ownership

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 Guidelines: §416.50(b)

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)

Survey Procedures: §416.50(b)

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

- 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*.

Q-0224

(Rev.)

§416.50(c) Standard: Advance Directives

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 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.

Interpretive Guidelines: §416.50(c)

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 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*:

- Information on the ASC's policies on advance directives;

- 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*
- 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:*

- *Clarify any differences between ASC-wide conscience objections and those that may be raised by individual ASC staff;*
- *Identify the state legal authority permitting such objection; and*
- *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.

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: §416.50(c)

- Review the ASC's policies and procedures related to the advance directive requirements. Do they conform to the regulatory requirements?
- 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?*
- If the State has an official advance directive form, ask the ASC to demonstrate how it provides these forms upon request to patients.
- 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*.
- Review each record in the survey sample to determine if advance directive information was provided *prior to the start of the surgical procedure*.
- *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?*

- 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?
- 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.

Q-0225

(Rev.)

§416.50(d) Standard: Submission and investigation of grievances

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:*

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

(5) 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.

(6) 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 Guidelines: §§416.50(d)(4), (5), & (6)

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.

- A complaint from someone other than a patient or a patient's representative *or surrogate* is not a grievance.
- 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 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 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: §§416.50(d)(4)(5), & (6):

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

Q-0226

(Rev.)

§416.50(d) Standard: Submission and investigation of grievances

.... *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.

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

Interpretive Guidelines: §§416.50(d)(1), (2), & (3)

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:

- Neglect - Failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness (42 CFR 488.301).
- 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 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: §§416.50(d)(1)(2), & (3)

- 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?
- 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?
- 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.
- 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.

Q-0227

(Rev.)

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

(1) The patient has the right to *the following*:

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

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

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: §416.50(e)(1)(i)

- *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.*

- 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.
- 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?

Q-0228

(Rev.)

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

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

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

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

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, 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: §416.50(e) (1)(ii)

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

Q-0229

(Rev.)

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

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

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

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

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

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

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that

their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure.

The ASC's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;
- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery (see guidance for §416.50(e)(2) & (3);
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and
- If the informed consent process and informed consent form are obtained outside the ASC, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

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

Example of a Well-Designed Informed Consent Process

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

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;

- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner will be performing important tasks related to the surgery, in accordance with the ASC's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the **ASC**.

Survey Procedures: §416.50(e)(1)(iii)

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

Q-0230

(Rev.)

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

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

(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 *Guidelines*: §§416.50(*e*)(2)& (3)

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.

Survey *Procedures*: §§416.50(*e*)(2) &(3)

- Verify that there is a policy addressing the exercise of rights on behalf of a patient judged legally incompetent.
- Verify that there is a policy addressing the delegation by a patient of the exercise of rights to a representative.

Q-0231

(Rev.)

§416.50(*f*) Standard: Privacy and Safety.

The patient has the right to –

(1) Personal privacy.

Interpretive *Guidelines*: §416.50(*f*)(1)

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: §416.50(f)(1)

- 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.

Q-0232

(Rev.)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(2) Receive care in a safe setting.

Interpretive Guidelines: §416.50(f)(2)

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: §416.50(f)(2)

- 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.
- 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.
- Observe the environment where care and treatment are provided.
- Review policy and procedures to see what steps the facility takes to curtail unwanted visitors and/or contaminated materials.
- Interview staff and patients to see if either have any concerns about the safety of the setting.

Q-0233

(Rev.)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

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

Interpretive Guidelines: §416.50(f)(3)

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 be 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: §416.50(f)(3)

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:

- 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?
- 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?
- Interview staff to determine if staff members know what to do if they witness abuse and neglect.
- 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.
- 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?

(Rev.)

§416.50(g) Standard: Confidentiality of Clinical Records

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

Interpretive Guidelines: §416.50(g)

Section 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 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:

- Notifying patients about their privacy rights and how their information can be used;
- Adopting and implementing privacy procedures for the ASC;
- Training employees so that they understand the privacy procedures;
- Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed within the ASC; and

- 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:

- 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.
- The policies and procedures of small ASCs may be more limited under the Rule than those of a very large ASC, 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), Office of Civil Rights, 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 that 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.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html>

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 throughout the ASC.

Survey Procedures: §416.50(g)

- What policies and procedures does the ASC have in place to prevent the release or disclosure of individually identifiable patient information?
- 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?
- What security measures are in place to protect the patient's medical records?

Q-0245

(Rev.)

§416.51(b) Standard: Infection control program.

[... The program is –]

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

Interpretive Guidelines: §416.51(b)(3)

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.,

- Maintenance of a sanitary environment; (See discussion of §416.51(a))
- Development and implementation of infection control measures related to ASC personnel;
- Mitigation of risks associated with patient infections present upon admission;
- Mitigation of risks contributing to healthcare-associated infections;
- Active surveillance;
- Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements;
- Plan evaluation and revision of the plan, when indicated;
- 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
- 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: §416.51(b)(3)

- Ask the infection control professional to describe actual examples of how, as a result of the action plan, infection control issues were identified and corrective or preventive actions were taken.
- Ask for documentation of how those actions were evaluated to assure that they resulted in improvement.
- 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.
- Does the plan address all the basic elements of infection control?
- *Ask the ASC's leadership how it tracks infections among patients and staff.*
- *Ask for documentation of this tracking – is there tracking of all patients?*
- *Ask the ASC's leadership what diseases are reportable to the State to verify the ASC's awareness of applicable reporting requirements.*
- *Ask the ASC if it has ever reported a reportable disease to the State. If yes, review the ASC's documentation of the case.*

Exhibit XXX

HOSPITAL RESTRAINT/SECLUSION DEATH REPORT WORKSHEET

A. Hospital Information:

Hospital Name: _____ CCN: _____
Address: _____ City: _____ State: _____ Zip Code: _____
Person Filing the Report: _____ Filer's Phone Number: _____

B. Patient Information:

Name: _____ Date of Birth: _____

Medical Record Number _____ Primary Diagnosis(es): _____

Date of Admission: _____ Date of Death: _____

Cause of Death: _____

C. Restraint Information (check only one):

- _____ While in Restraint, Seclusion, or Both
_____ Within 24 Hours of Removal of Restraint, Seclusion, or Both
_____ Within 1 Week, Where Restraint, Seclusion or Both Contributed to the Patient's Death

Type (check all that apply): Physical Restraint _____ Seclusion _____ Drug Used as a Restraint _____

If Physical Restraint(s), Type (check all that apply):

- | | |
|--------------------------------------|-------------------------------------|
| _____ 01 Side Rails | _____ 08 Take-downs |
| _____ 02 Two Point, Soft Wrist | _____ 09 Other Physical Holds |
| _____ 03 Two Point, Hard Wrist | _____ 10 Enclosed Beds |
| _____ 04 Four Point, Soft Restraints | _____ 11 Vest Restraints |
| _____ 05 Four Point, Hard Restraints | _____ 12 Elbow Immobilizers |
| _____ 06 Forced Medication Holds | _____ 13 Law Enforcement Restraints |
| _____ 07 Therapeutic Holds | _____ 14 Other |

If Drug Used as Restraint: Drug Name _____ Dosage _____

ASC INFECTION CONTROL SURVEYOR WORKSHEET

Name of State Agency or AO (please *specify*) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (e.g., the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code _____

Address

City

State

Zip

3. 10-digit CMS Certification Number

--	--	--	--	--	--	--	--	--	--

4. What year did the ASC open for operation?

y	y	y	y

5. Please list date(s) of site visit:

		/			/					to			/			/				
m	m		d	d		y	y	y	y		m	m		d	d		y	y	y	y

6. What was the date of the most recent previous federal (CMS) survey:

		/			/				
m	m		d	d		y	y	y	y

7. Does the ASC participate in Medicare via accredited "deemed" status?

- ☐ YES
☐ NO

7a. If YES, by which CMS-recognized accreditation organization(s)?

- ☐ Accreditation Association for Ambulatory Health Care (AAAHC)
☐ American Associate for Accred. of Ambulatory Surgery Facilities (AAAASF)
☐ American Osteopathic Association (AOA)
☐ The Joint Commission (TJC)

7b. If YES, according to the ASC, what was the date of the most recent accreditation *survey*?

		/			/				
m	m		d	d		y	y	y	y

8. What is the ownership of the facility? **(SELECT only ONE bubble)**

- ☐ Physician-owned
☐ Hospital-owned
☐ National corporation (including joint ventures with physicians)
☐ Other (please *specify*):

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)? **(SELECT only ONE bubble)**

- ☐ Dental
☐ Endoscopy
☐ Ear/Nose/Throat
☐ OB/Gyn
☐ Ophthalmologic
☐ Orthopedic
☐ Pain
☐ Plastic/reconstructive
☐ Podiatry
☐ Other (please *specify*):

10. What additional procedures are performed at the ASC? **(SELECT all that apply)**
Do not include the procedure type indicated in question 9.

- ☐ Dental
☐ Endoscopy
☐ Ear/Nose/Throat
☐ OB/Gyn
☐ Ophthalmologic
☐ Orthopedic
☐ Pain
☐ Plastic/reconstructive
☐ Podiatry
☐ Other (please *specify*):
☐ N/A

11. Who does the ASC perform procedures on? **(SELECT only ONE bubble)**

- ☐ Pediatric patients only
☐ Adult patients only
☐ Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC per month?

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 per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

- | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9+ |

Number actively maintained:

- | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9+ |

14. Please indicate how the following services are provided: **(select all that apply)**

	Contract	Employee	Other	If Other, please <i>specify</i> :
Anesthesia/ <i>Analgesia</i>	☐	☐	☐	
Environmental Cleaning	☐	☐	☐	
Linen	☐	☐	☐	
Nursing	☐	☐	☐	
Pharmacy	☐	☐	☐	
Sterilization/Reprocessing	☐	☐	☐	

Waste Management	☐	☐	☐	
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INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?

- ☐ YES
☐ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

16. Does the ASC's infection control program follow nationally recognized infection control guidelines?

- ☐ YES
☐ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

- ☐ YES
☐ NO

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.

16b. If YES to (a), which nationally-recognized infection control guidelines has the ASC selected for its program?
(**Select all that apply**)

- ☐ CDC/HICPAC Guidelines:
- ☐ Guideline for Isolation Precautions (CDC/HICPAC)
 - ☐ Hand hygiene (CDC/HICPAC)
 - ☐ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
 - ☐ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)
 - ☐ Perioperative Standards and Recommended Practices (AORN)
 - ☐ Guidelines issued by a specialty surgical society / organization (List)

Please specify (please limit to the space provided):

- ☐ Others

Please specify (please limit to the space provided):

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program? ☐ YES ☐ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an: ☐ ASC employee
(**Select only ONE bubble**) ☐ ASC contractor

17b. Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) **does not** require that the individual be certified in infection control.) ☐ YES ☐ NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program?

--	--

 hours per week

(Note: §416.51(b)(1) **does not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? ☐ YES ☐ NO

NOTE! If the ASC does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) **must** be cited.

18a. If YES, how does the ASC obtain this information? (**Select ALL that apply**)

- ☐ The ASC sends e-mails to patients after discharge
- ☐ The ASC follows-up with their patients' primary care providers after discharge
- ☐ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
- ☐ Other (please **specify**):

--

18b. Is there supporting documentation confirming this tracking activity? ☐ YES ☐ NO

NOTE! If the ASC does not **have supporting documentation**, a deficiency related to 42 CFR 416.51(b)(3) **must** be cited.

18c. Does the ASC have a policy/procedure in place to comply with State ☐ YES

notifiable disease reporting requirements?

☐ NO

NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to **42 CFR 416.51(b)(3)**. CMS does not specify the means for reporting; generally this would be done by the State health agency.

☐ YES

19. Do staff members receive infection control training?

If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.

☐ NO

19a. If YES, how do they receive infection control training?
(**Select all that apply**)

- ☐ In-service
☐ Computer-based training
☐ Other (please specify):

19b. Which staff members receive infection control training?
(**Select all that apply**)

- ☐ Medical staff
☐ Nursing staff
☐ Other staff providing direct patient care
☐ Staff responsible for on-site sterilization/high-level disinfection
☐ Cleaning staff
☐ Other (please specify):

19c. Is training:

- ☐ the same for all categories of staff
☐ different for different categories of staff

19d. Indicate frequency of staff infection control training
(**Select all that apply**)

- ☐ Upon hire
☐ Annually
☐ Periodically / as needed
☐ Other (please specify):

19e. Is there documentation confirming that training is provided to all categories of staff listed above?

☐ YES
☐ NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b) and (b)(3).

20. How many procedures were observed during the site visit?

☐ 1

☐ 2

☐ 3

☐ 4

☐ Other

If other, please **specify** the number:

procedures

PART 2 – INFECTION CONTROL & RELATED PRACTICES

INSTRUCTIONS:

- Please **select ONE bubble** for each “Was Practice Performed?” and “Manner of Confirmation” question, unless otherwise noted.
- If N/A is **selected**, please explain why there is no associated observation, or why the question is not applicable, in the COMMENTS box at the end of each section.

I. Hand Hygiene

Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).

Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Unless otherwise indicated, a “No” response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. All patient care areas have:		
Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is “No.”		
a. Soap and water available	☐ Yes ☐ No	☐ Observation ☐ Interview ☐ Both
b. Alcohol-based hand rubs available	☐ Yes ☐ No	☐ Observation ☐ Interview ☐ Both
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. (There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs)	☐ Yes ☐ No	
B. Staff perform hand hygiene:		
a. After removing gloves	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
<i>b. Before direct patient contact</i>	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
<i>c. After direct patient contact</i>	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
<i>d. Before performing invasive procedures (e.g. placing an IV)</i>	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
<i>e. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)</i>	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
C. Regarding gloves, staff:		
a. Wear gloves for procedures that might involve contact with blood or body fluids	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
b. Wear gloves when handling potentially contaminated patient equipment	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
c. Remove gloves before moving to the next tasks and/or patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
D. Additional breaches in hand hygiene, not captured by the questions above, were identified (If YES, please specify further in comments)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Comments: (please <i>specify</i>)		

II. Injection Practices (injectable medications, saline, other infusates)

Observations are to be made of staff *preparing* and *administering* medications and *performing* injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Needles are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
B. Syringes are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
D. Medication vials are always entered with a new needle	☐ No ☐ N/A	☐ Interview ☐ Both
E. Medication vials are always entered with a new syringe	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
F. Medications that are pre-drawn are labeled with the <i>date and</i> time of draw, initials of the person drawing, medication name, strength and <i>discard</i> date <i>and</i> time	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
b. Manufactured prefilled syringes are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
c. Bags of IV solutions are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
d. Medication administration tubing and connectors are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
H. Multi-dose injectable medications are used for only one patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
(Note: a “No” answer here is not necessarily a breach in infection control and does not result in a citation. However, a “No” response to <i>either or both of</i> the related questions I and J should be cited). (Fill in N/A if no multi-dose medications/infusates are used). If YES, please skip to “K” If NO, please answer “I and J”:		
I. Multi-dose vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the discard date as per ASC policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the ASC.	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
J. Multi-dose medications used for more than one patient are <i>stored and accessed away from</i> the immediate areas where direct patient contact occurs	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
K. All sharps are disposed of in a puncture-resistant sharps container	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
L. Sharps containers are replaced when the fill line is reached	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
M. Additional breaches in injection practices, not captured by the questions above were identified (If YES, please specify further in comments)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Comments: (please <i>specify</i>)		

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff *performing* equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

*Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

STERILIZATION

A. Critical equipment is sterilized	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
B. Are sterilization procedures performed on-site? (If NO, skip to “F”)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

(A “No” answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

a. If YES to B, please indicate method of sterilization:	☐ Steam autoclave ☐ Peracetic acid ☐ Other (please <i>specify</i>):	
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Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization	☐ Yes	☐ Observation
D.	☐ Yes	☐ Observation
a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	☐ No	☐ Interview
	☐ N/A	☐ Both
b. A chemical indicator is placed in each load	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
c. A biologic indicator is performed at least weekly and with all implantable loads	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both
H. Additional breaches in sterilization practices not captured by the questions above were identified (If YES, please specify further in comments)	☐ Yes	☐ Observation
	☐ No	☐ Interview
	☐ N/A	☐ Both

Comments: (please <i>specify</i>)	
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HIGH-LEVEL DISINFECTION

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Semi-critical equipment is high-level disinfected or sterilized	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
B. Is high-level disinfection performed on site? (If NO, Skip to "F")	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)		
(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. If answer to B was YES, please indicate method of high-level disinfection:	☐ Manual ☐ Automated ☐ Other (please <i>specify</i>):	
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
b. High-level disinfection equipment is maintained according to manufacturer instructions	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
II. Tested for appropriate concentration according to manufacturer's instructions	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
III. Replaced according to manufacturer's instructions	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
IV. Documented to have been prepared and replaced according to manufacturer's instructions	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions <i>or</i> evidence-based guidelines	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
E. Items that undergo high-level disinfection are allowed to dry before use	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
G. Additional breaches in high-level disinfection practices, not captured by the questions above were identified (If YES, please specify further in comments)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Comments: (please <i>specify</i>)		

IV. Environmental Infection Control

Observations are to be made of staff **performing** environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

*Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
B. Operating rooms are terminally cleaned daily	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (If YES, please specify further in comments)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Comments: (please specify)		

V. Point of Care Devices (e.g., blood glucose meter)

Observations are to be made of staff **performing** fingerstick testing (e.g., nurses)

If N/A is **selected**, please clarify in the comments box below why it was not applicable or not observed.

Unless otherwise indicated, a “No” response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
1. Does the ASC have a point of care device, such as a blood glucose meter? If NO, STOP HERE.	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
A. A new single-use, auto-disabling lancing device is used for each patient	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
B. <i>If used for more than one patient, the point of care device is cleaned and disinfected after every use according to manufacturer’s instructions.</i>	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
<i>Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the device must not be used for more than one patient.</i>		
C. Additional breaches in appropriate use of point of care devices (like glucose meters) not captured by the questions above were identified (If YES, please specify further in comments)	☐ Yes ☐ No ☐ N/A	☐ Observation ☐ Interview ☐ Both
Comments: (please specify)		