Ambulatory Surgical Centers
Frequently Asked Questions

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General

Q1. Do I need to notify the state when I make changes at my ASC (such as changes of ownership, changes in location, etc.)?

A1. Yes. Most change processes can be found on the Non-Long Term Provider's page of the BFS web site.

Q2. What is the survey frequency for ASCs in Idaho?

A2. ASCs are surveyed per the direction of CMS. Current CMS direction can be found in the ASC survey process section of the Non-Long Term Provider's page of the BFS web site.

Q3. Are ASCs licensed in the State of Idaho?

A3. No. In the State of Idaho, ASC are Federally Certified only.

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§416.2 Definitions

Q1. What are the separation requirements for an ASC that shares a physical location with a physician's office?

A1. The regulation at Q02 addresses distinct entity requirements for ASCs. Additional information can also be found in the CMS Survey and Certification letter S&C-10-20-ASC, dated May 21, 2010.

Q2. If an ASC is within a physician's office, must it have a separate entrance?

A2. No. The ASC and the physician office must be separate entities and have separate waiting rooms but they may share a common entrance.

Q3. Are there any time limits for surgeries in ASCs?

A3. Yes. In accordance with Q02, an 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.

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§416.40 Condition for Coverage: Compliance with State Licensure Laws

Q1. Must a health facility employee report suspected child abuse, or is the legal obligation restricted to observed acts?

A1. The reporting requirement extends to health care workers “having reason to believe” that a child has been abused, neglected or abandoned, as well as those who observe conditions or circumstances [Idaho Code 16-1619 (a)]. Therefore, a health facility employee and anyone else who suspects or observes abuse, is required to report.

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§416.41 Condition for Coverage: Governing Body and Management

Q1. Are CRNAs required to register with the DEA if they intend to independently administer controlled substances, or do CRNAs needed such a registration only if they intended to prescribe?

A1. A CRNA may not independently administer, dispense, or prescribe controlled substances without being registered with DEA.

Title 21 CFR §130l.22(b) states: "(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself."

Although this regulation does allow an agent or employee of a DEA registered practitioner, including a CRNA, to administer or dispense (but not prescribe) a controlled substance without having to obtain a separate DEA registration while acting in the normal course of business or employment, it

is important to note that "administer," as defined in 21 USC §802(2), places limits on the actions of this agent or employee:

"(2) The term 'administer' refers to the direct application of a controlled substance to the body of a patient or research subject by (A) a practitioner (or, in his presence, by his authorized agent), or (B) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means."

Consequently, if a CRNA intends to administer a controlled substance, and said administration will not be in the presence of the practitioner, then the CRNA is independently administering a controlled substance and therefore must be separately registered with DEA prior to any such administration.

For additional information regarding the DEA's Diversion Control Program, please visit the website at www.DEAdiversion.usdoj.gov.

Furthermore, in addition to DEA registration, a CRNA must also obtain a Controlled Substance Registration from the Idaho Board of Pharmacy.

Q2. Are physicians required to have admitting privileges at a hospital in the event that a patient requires emergency medical care beyond the capabilities of the ASC?

A2. No. The Federal regulation at Q42 requires the ASC to have a written transfer agreement with an appropriate hospital **or** ensure that all physicians performing surgery in the ASC have admitting privileges at an appropriate hospital.

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§416.42 Condition for Coverage: Surgical Services

Q1. Is Idaho exempted from the requirement for physician supervision of CRNAs in accordance with Q-0063?

A1. Yes. CMS was notified of Idaho's election for a state exemption as of March 8, 2002.

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§416.43 Condition for Coverage: Quality Assessment and Performance Improvement

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§416.44 Condition for Coverage: Environment

Q1. Can surgical blades marked "single-use" be reprocessed?

A1. In accordance with the interpretive guidance at Q241, some devices marked for single use can be reprocessed. However, the single use device must be sent to an FDA-approved vendor for reprocessing.

Q2. How often does operating room equipment need to be inspected?

A2. Per the interpretive guidance at Q101, the OR equipment must be inspected, tested and maintained by the ASC in accordance with Federal and State law (including regulations) and manufacturer's recommendations.

Q3. What is the acceptable humidity level for ORs?

A3. CMS expects ASCs to follow the instructions for use for the sterile supplies and electro-medical equipment used in the operating rooms. For additional information, please refer to the CMS S&C 15-27 letter, dated 2/20/15.

Q4. What emergency equipment is required in an ASC?

A4. No specific list of emergency equipment is specified in the regulations. However, as stated in the interpretive guidance at Q105, 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.

Q5. There is a recommendation for ACLS renewal, but no actual expiration date. What are the regulatory requirements for ACLS renewal?

A5. The Interpretive Guidance at Q105 states "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…"

If the facility chooses not to follow the ACLS renewal recommendation, the facility's policies must include what the facility has determined to be an appropriate renewal timeframe and the reasoning behind the decision.

Q6. Is there a standard or CfC that covers TV monitors stating that all equipment, including monitors in ORs and other locations in patient care areas of health care facilities have to be listed/labeled for the intended use and therefore need to be listed/labeled for health care use or listed as a part of a system that is listed/labeled for health care use (e.g. part of a digital viewing system by a vendor)?

A6. The Federal regulations include the Q100 Condition For Coverage: Environment at 416.44. The regulations under that Condition require "Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area." Further, the Interpretive Guidelines at §416.44(a)(1) states "…Operating rooms must be designed in accordance with industry standards for the types of surgical procedures performed in the room..." Listings become a concern with LSC when they are in the patient care vicinity and the cord is connected to the patient or when it does not have a grounded plug. Electrical equipment within the patient care vicinity would be reviewed to ensure it is grounded and checked for the latest biomed testing label to ensure it is regularly checked for safety and current leakage by bio medical staff.

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§416.45 Condition for Coverage: Medical Staff

Q1. **How often do reappraisals need to be done?**

A1. The regulations do not specify a specific timeframe. However, the interpretive guidance at Q122 states "CMS recommends a reappraisal at least every 24 months."

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§416.46 Condition for Coverage: Nursing Services

Q1. Would having a CRNA caring for a patient who is receiving anesthesia meet the nursing staffing requirements if no other patients are in the ASC?

A1. The regulations require the ASC to have an RN available at all times a patient is in the ASC. In the scenario described, only one patient is being cared for. The regulations are silent about the specific situation in question. CMS believes the intent of the regulation to have an RN immediately available for emergency responses would be met by the CRNA in the case described. If any other patients were receiving care in any other part of the ASC, a second RN would be necessary; as the CRNA would not be immediately available should an emergency arise with the second patient.

Q2. The CMS requirements state "There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC." Would it be acceptable to have a PA in place of the RN?

A2. No. The regulation at Q141 specifically requires an RN.

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§416.47 Condition for Coverage: Medical Records

Q1. Is there a specific form that needs to be used for operative reports?

A1. No. The Federal regulation at Q162 specifies what information is required to be in the medical records, but does not prescribe a specific form which must be used.

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§416.48 Condition for Coverage: Pharmaceutical Services

Q1. Are Physician's Assistants (PAs) considered licensed independent practitioners for the purposes of medication administration?

A1. No. In accordance with the Idaho Board of Medicine rules governing PAs (IDAPA 22.01.03), PAs are not licensed independent practitioners in Idaho as they are an agent of, and work under the supervision of, a licensed physician. The supervising physician must review patient care with the PA

at least monthly and periodically review a representative sample of records completed by the PA.

Additionally, there must be a Delegation of Service Agreement. This agreement defines the services (scope of practice) that the supervising physician has agreed to delegate to the PA and should be consistent with the expertise and regular scope of practice of the supervising physician.

Q2. Is there a standard stating how long multi-dose vials are good for after they are opened?

A2. Yes. United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multi-dose vial has been opened or accessed, the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened vial.

Q3. Do controlled substances need to be double locked?

A3. No. The ASC regulation at Q180 requires drugs and biologicals to be stored in a safe manner. When determining effective controls and procedures to prevent against diversion of controlled substances the Idaho Board of Pharmacy and the DEA both use any or all of the security requirements set forth in CFR §1301.72-1301.76.

CFR, §1301.75(b) states that controlled substances in Schedules II-V shall be stored in a securely locked, substantially constructed cabinet. There is no specific requirement that mandates a “double lock & key.” However, access of controlled substances is to be restricted to a minimum number of authorized individuals. Recognizing that unauthorized individuals may need to access locked medication rooms, nurses' stations, or other drug storage room locations, it is logical to further restrict the controlled substances within the drug storage room; thus the “double lock and key” expression.

Q4. Are CRNAs required for the administration of Propofol when it is used for moderate or conscious sedation?

A4. No. In accordance with the interpretive guidance at Q101, a physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the

supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.

The Idaho Board of Nursing Rules do not expressly prohibit RNs from administering moderate or conscious sedation. A trained RN, under the direct supervision of a qualified physician or anesthesiologist, can administer moderate or conscious sedation if the RN has no other duties than to monitor the patient and the ASC's policies permit it.

Q5. Is there any guidance regarding the appropriate disposal of medications?

A5. Yes. Both the FDA and DEA include drug disposal information.

Q6. Due to drug shortages, we are not always able to replace emergency medications when they expire. The expired medications are kept until they can be replaced as even expired medications are better than having nothing during an emergency situation. Will this practice always result in a citation?

A6. No. In cases of medication shortages, the facility must have documentation regarding their attempts to obtain the medication and a plan in place to address a prolonged shortage. For additional information on current drug shortages, please refer to the Drug Shortage Index can be found on the FDA website.

Q7. Is it acceptable for meds to be drawn from multi-dose vials in the OR, as this is a patient care area?

A7. Typically, it is not acceptable for multi-dose vials to be drawn in the OR. However, the regulation at Q181 requires drugs to be prepared and administered according to established policies and acceptable standards of practice. There are specific situations that include the use of multi-dose vials in the patient care area as a standard of practice. For example, the use of multi-dose eye drops administered using the APIC "No touch method" is a nationally recognized standard of practice. The facility policies would be required to reflect the nationally recognized standard and periodically review its use to ensure the method continued to be recognized and accepted. Additionally, the facility is required to continuously monitor and evaluate the practice to ensure it is being implemented correctly and safely as part of the facility's total infection control and QAPI programs.

Q8. Are ASCs required to label saline bags and tubing?

A8. While it is always good practice to date and time the saline bag, the regulation at Q180 states the ASC must provide drugs and biologicals in a safe and effective manner. For a time-limited procedure where the saline is not adulterated for a specific patient and the IV is not going to infuse over an extended time period, labeling may not be required as long as the saline was being administered safely and effectively. Additionally, the practice would be required to be incorporated into facility policy and reflective of nationally recognized standards of practice.

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§416.49 Condition for Coverage: Laboratory and Radiology Services

Q1. How often does radiology equipment need to be inspected?

A1. Per the interpretive guidance at Q202, radiology equipment must be inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and facility policy.

Q2. Are dosimetry badges and shielding required when using fluoroscopic equipment?

A2. Yes. The Federal regulation at Q202 requires radiologic services meet professionally approved standards for safety.

Additionally, the Idaho Radiation Control Rules (IDAPA 16.02.27) require the use of dosimetry badges and shielding of operators unless they can demonstrate that under normal usage there would be no (zero) exposure to operators of said equipment. Zero exposure would need to be established by using dosimetry for a one year period with no exposure recorded. Only then would a written exemption be issued which would be kept on file at the facility.

Q3. Does the State of Idaho have standards in place for the receiving of Allografts for surgical procedures in an ASC?

A3. Idaho does not have State licensure rules for ASCs and we are not aware of Idaho allograft requirements beyond those established by the FDA. There are some instances where donors are tested for various infectious diseases

prior to donation and that testing is covered by CLIA regulation. In Idaho, that would be regulated by the Idaho Bureau of Laboratories.

Additionally, the ASC Federal regulations do not specifically address requirements for the shipping and receiving of graft materials. However, regulatory requirements related to Lab services (Q200) and the Conditions for Coverage for Governing Body (Q40) require that the facility policies and programs are administered so as to provide quality healthcare in a safe environment. Should concerns regarding the receipt, storage, and use of allografts be identified during the survey process, those regulatory requirements as well as others (e.g. Condition for Coverage Surgical Services, etc.) may be cited.

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§416.50 Condition for Coverage: Patient Rights

Q1. Can you please provide me with the contact information for the state representative to whom patients and/or their representatives can report complaints as required in Q0222, Notice of Rights?

A1. Complaints can be made to:

Bureau of Facility Standards
Non-Long Term Care Co-Supervisor
PO Box 83720
Boise, ID 83720-0036
(208) 334-6626 Option 4

Q2. Must ASCs honor patients' advanced directives?

A2. No. Since ASCs are facilities that primarily perform elective surgeries, ASCs may choose to adopt a policy that does not support advanced directives in their facility for elective procedures. However, the facility and its policy must reflect the acknowledgement and implementation of the patient's advanced directive wishes in the event a patient is transferred to a hospital for unanticipated emergency treatment. It is the intent of the rule that patients be able to make informed decisions regarding their care, including the right to execute advanced directives. It was never the intent to allow a blanket advanced directive refusal policy. The ASC must address advanced directives even if they do not wish to honor them except in the event of an emergency transfer. This must also be clearly communicated to the patient.

Q3. Are patients required to sign the Notice of Rights indicating their understanding of their rights as patients?

A3. No. While some ASCs use this method to document the patients' understanding of rights, it is not required by the ASC regulations.

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§416.51 Condition for Coverage: Infection Control

Q1. Is it permissible to repackage single-dose vials or single use vials into smaller doses, each intended for a single patient?

A1. Yes, under very specific guidelines. Please refer to CMS Survey and Certification letter S&C-12-35-ALL, dated June 15, 2012 for additional information.

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§416.41 Condition for Coverage: Patient Admission, Assessment and Discharge

Q1. Can a CRNA complete the H&P?

A1. Yes. The Federal Regulation at Q0261 states the H&P has to be completed by the physician or another "qualified practitioner in accordance with applicable state health and safety laws, standards of practice, and ASC policy." In accordance with the Idaho Board of Nursing Rules, CRNAs are considered an advanced practitioner. Therefore, completing the H&P is within their scope of practice in Idaho and may be done as long as the ASC's policies permit it.

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