



# CMS' Interpretive Guidelines: How to Comply with Recent Changes

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# Learning Objectives

- Explain an ASCA-driven clarification to the physician discharge language
- Interpret the changes to the radiologist on staff guidelines
- Explain the new guidance on other topics in the recent update on the Interpretive Guidelines (emergency transfers, transfer agreements, informed consent, definition of an operating room)
- Discuss the status of the Center for Medicare and Medicaid Services (CMS) proposal to increase ASC emergency preparedness requirements

# CMS' Interpretive Guidelines (IGs)

- First revision since 2013
- <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-22.pdf>
- The above link only includes the revised sections of the IGs

# CMS' Interpretive Guidelines Revisions

- §416.41(b)(1) Hospitalization (transfers)
- §416.44 (a)(1) Physical Environment (operating rooms/procedure rooms)
- §416.44 (a)(1) Physical Environment (humidity)
- §416.49 (b)(1)(2) Radiologic Services
- §416.50 (a) Notice of rights
- §416.50 (e) Exercise of rights and respect for property and person
- §416.52 (c)(2) Discharge

# §416.41(b) Hospitalization

## Q-0042

- (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.
- (2) This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter.
- (3) The ASC must –
  - i. Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or
  - ii. Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

# §416.41(b)(1)

## Immediate Transfer Procedure

An “effective procedure” for immediate emergency transfers includes:

- Written ASC policies and procedures that address the circumstances warranting emergency transfer, including who makes the transfer decision; the documentation that must accompany the transferred patient; and the procedure for accomplishing the transfer safely and expeditiously, ***including communicating with the receiving hospital.***
- Arrangement for immediate emergency transport of the patient. (It is acceptable if the ASC contacts the ambulance service via 911 to arrange emergency transport, unless State licensure requires additional arrangements, ***but the ASC is still responsible for communicating with the receiving hospital to facilitate the transfer.***)

# §416.41(b)(2)

## Transfer to a local hospital

- If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the type of surgeries performed by the ASC, ***another hospital that is able to do so and which is closer than other comparable hospitals would*** meet the “local” definition. ***For example, if there is a long term care hospital within five miles of the ASC, and a short-term acute care hospital providing emergency services within fifteen miles of the ASC, the ASC would be expected to transfer patients to the short-term acute care hospital.***
- ***Patient-specific circumstances play a role in determining the appropriate local hospital at the time of an emergency. For example, if the patient had a heart attack during surgery at the ASC and needs an interventional cardiac catheterization, and the closest hospital does not offer this service, it is expected that the ASC would transfer the patient to a farther hospital with the cardiac catheterization capability.***

# §416.41(b)(2)

## Transfer to a local hospital, Contd.

- *If there are multiple hospitals with comparable capabilities that are roughly the same distance from the ASC, i.e., there are only a few miles difference among them in their distance from the ASC, then the ASC may make the transfer to any one of these hospitals. For example, if there are three comparable, appropriate hospitals within a ten mile radius of the ASC, transfer to any one would be acceptable. Likewise, for another example, if the ASC is in a more rural area and there are two appropriate hospitals that are each about 40 miles distant from the ASC, but in opposite directions, each of those hospitals would be considered a “local” hospital for the ASC.*
- *On the other hand, for example, if there is an appropriate hospital eight miles from the ASC, and another hospital with similar capabilities twenty miles from the ASC, the further hospital would not be considered a local hospital for ASC emergency transfer purposes, unless the closer hospital lacks capacity at the time of the transfer.*
- *CMS expects that, absent the specific types of circumstances described above, emergency transfers will ordinarily be made to a hospital with which the ASC has an arrangement(s) to meet the requirements of §416.41(b)(2) and (3). Regardless of any business issues that may arise between ASCs and their local hospital(s), the ASC is required **to have an effective procedure to immediately** transfer its emergency cases to the nearest, most appropriate local hospital, since a delay in transfer could affect the patient’s health. (See 72 FR 50472, August 31, 2007 and 73 FR 68714, November 18, 2008.)*

# §416.41(b) Hospitalization, Survey Procedures

- *Before going on the survey, determine which hospital(s) in the vicinity of the ASC might meet the regulatory requirement of being a local hospital.*
- *Determine whether the ASC has a transfer agreement with an appropriate local hospital that meets the regulatory requirements. If it does, ask to see the transfer agreement. Look for an expiration date. If there is no expiration date, ask the ASC whether the transfer agreement has been terminated by either party. If there is doubt about the transfer agreement being in effect, a surveyor may contact the hospital to ask it whether it has a current transfer agreement with the ASC.*
- *If the ASC does not have a transfer agreement with an appropriate local hospital, ask for documentation that each physician who has privileges to perform surgery in the ASC has admitting privileges in an appropriate local hospital. Ask the ASC how it ensures that its information is up-to-date.*
- *If the ASC transfers emergency cases to hospital(s) other than local one(s), ask for the rationale supporting these alternative transfers.*

## §416.44 (a)(1) Physical Environment (operating rooms/procedure rooms), Q-0101

- CMS expands the definition of operating room (OR) to include “***not only traditional ORs, but also procedure rooms, including those where surgical procedures that do not require a sterile environment are performed.***”
- Intent was possibly to clarify that procedure rooms are not held to all of the same standards as traditional ORs.

## §416.44 (a)(1) Physical Environment (operating rooms/procedure rooms), Q-0101

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

## §416.44 (a)(1) Physical Environment (operating rooms/procedure rooms), Q-0101

*The OR must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.). Medical equipment for the OR includes the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into consideration the time required for appropriate cleaning and, if applicable, sterilization. In addition, emergency equipment determined to be necessary in accordance with §416.44(c) must be either in or immediately available to the OR.*

## §416.44 (a)(1) Physical Environment (humidity), Q-0101

- (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

# §416.44 (a)(1) Physical Environment (humidity), Q-0101 Interpretive Guidelines

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

# §416.44 (a)(1) Physical Environment (humidity), Q-0101

- In April 2013, CMS issued a categorical waiver of the Life Safety Code that would allow facilities to lower the minimum RH from 30% to 20% for anesthetizing locations, including operating rooms. The maximum RH remained at 60%. ASCs were included in this waiver.
- Relative humidity can impact the shelf life and product integrity of sterile supplies as well as the operation of some electro-medical equipment used in the OR, particularly with older model electro-medical equipment.
- A group of health care societies, including ASCA, met last October in order to establish a joint statement offering information and suggestions for facilities when establishing or adjusting relative humidity levels to below 30%.

## §416.44 (a)(1) Physical Environment (humidity), Q-0101 Recommendations

- Before establishing RH levels below 30% in the OR, ASCs should assess the impact of lower RH on the equipment and supplies being used.
- Personnel should understand the manufacturer's Instructions for Use (IFU) specific to all supplies and equipment, and in particular know what environmental humidity requirements are specified in the IFU.
- [http://www.aami.org/news/2015/010915\\_Press\\_Joint\\_Communication\\_Addresses\\_Challenge\\_Humidity\\_Levels\\_OR.html](http://www.aami.org/news/2015/010915_Press_Joint_Communication_Addresses_Challenge_Humidity_Levels_OR.html)

# §416.49 (b)(1) Radiologic Services, Q-0202

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

# §416.49 (b)(1) Radiologic Services, Q-0202

## Interpretive Guidelines

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

# §416.49 (b)(1) Radiologic Services, Q-0202

## New Survey Procedures

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

# §416.49 (b)(1) Radiologic Services, Q-0202

## Recommendations

- Have the center's Governing Board define and approve what radiologic services will be provided at the center.
- Document this approval in the Governing Board's meeting minutes as well as the center's policy

# §416.49 (b)(1) Radiologic Services, Q-0203

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

# §416.49 (b)(1) Radiologic Services, Q-0203 Interpretive Guidelines

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

# §416.49 (b)(1) Radiologic Services, Q-0203

## New Survey Procedures

- *If the ASC provides radiologic services as an integral part of surgical procedures, does it comply with the requirements of §482.26(b), (c)(2), and (d)(2) in its provision of those services, using the hospital radiologic services interpretive guidelines cited above?*
- *Interview the individual designated responsible for assuring compliance with this CfC and review related documentation to assess how these responsibilities have been implemented in the ASC. What steps are available to this individual to remedy the situation if there is evidence of noncompliance with any of the requirements?*

# §416.49 (b)(1) Radiologic Services, Q-0203

## Recommendations

- Review §482.26(b), (c)(2), and (d)(2)
- The person who is designated by the center's Governing Board to oversee the radiological services needs to be aware of their responsibilities that are outlined in the above sections.
- These responsibilities need to be outlined in the center's policy as well as the delineation of privileges or job description of the person.

## §416.49 (b)(2) Radiologic Services, Q-0204

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

# §416.49 (b)(2) Radiologic Services, Q-0204 Interpretive Guidelines

- *If the ASC provides radiologic services, the ASC's governing body must appoint an individual who has appropriate qualifications, in accordance with State law and Federal regulations, to provide oversight of these services. The appointed individual is responsible for assuring the ASC's compliance with §§ 482.26(b), (c)(2), and (d)(2).....*

# §416.49 (b)(2) Radiologic Services, Q-0204

## New Survey Procedures

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

# §416.49 (b)(2) Radiologic Services, Q-0204

## Recommendations

- Have the center's Governing Board approve who will be responsible for overseeing the center's radiological services.
- The Governing Board needs to be aware of the appropriate state requirements as well as §482.26(b), (c)(2), and (d)(2) of the Interpretive Guidelines. (the more strict requirements are the ones to use)
- Document this approval in the Governing Board's meeting minutes as well as the center's policy.
- The person who is designated by the center's Governing Board to oversee the radiological services needs to be aware of their responsibilities that are outlined in the above sections.
- These responsibilities need to be outlined in the center's policy as well as the delineation of privileges or job description of the person.

## §416.50 (a) Notice of rights Q-0221

- ASCs must provide in their notice of rights the website for the Office of the Medicare Beneficiary Ombudsman.
- CMS has updated the interpretive guidelines to include the current website:  
*<http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html>*

## §416.50 (e) Exercise of rights and respect for property and person, Q-0229

- Informed consent must be obtained and the informed consent form must be *signed by the patient, or as appropriate, the patient's representative.*
- Survey procedures: §416.50(e)(1)(iii) : *Was the consent signed by the patient or as appropriate, the patient's representative?*

## §416.52 (c)(2) Discharge, Q-0266

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

## §416.52 (c)(2) Discharge, Q-0266 Interpretive Guidelines

- *It is permissible for the operating physician to write a discharge order indicating “the patient may be discharged when stable.” (73 FR 68721). In such cases there must be documentation of when patient was stable. It is expected that a patient will actually leave the ASC within 15 – 30 minutes of the time when the physician signs the discharge order or when he or she was found to be stable, whichever happens later.*

# §416.52 (c)(2) Discharge Q-0266

## Recommendations

- Make certain the physician who performed the surgery/procedure signs a discharge order.
- The center's policies should outline the discharge process and criteria, if applicable.

# ASC Infection Control Surveyor Worksheet

- Surveyors will use this document during the on-site survey in order to determine compliance with the Infection Control Condition for Coverage.
- Make certain you are using the worksheet for ASCs and *NOT HOSPITALS*
- [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf)

# Overall Recommendations

- Periodically review state regulations for revisions
- The more strict regulation (state vs. Medicare) is the one that needs to be followed.
- Any revision(s) that is made to a process or procedure at the center, that policy would need to be updated.
- All revised policies need to be approved by the center's Governing Board and this documented in the meeting minutes.

# Update on Other Potential Changes

- Life Safety Code (LSC)
- Emergency Preparedness

# Life Safety Code (LSC)

- Proposed adoption of 2012 edition of the LSC
- Windowless anesthetizing locations: “ASC must have a supply and exhaust system that (i) Automatically vents smoke and products of combustion, (ii) Prevents recirculation of smoke originating within the surgical suite, and (iii) Prevents the circulation of smoke entering the system intake.”

# Emergency Preparedness

## § 416.41(c)

Since November 2008, requires ASCs to have a disaster preparedness plan. ASCs must:

- (1) have a written disaster plan for the emergency care of patients, staff and others in facility;
- (2) coordinate with state and local authorities; and
- (3) conduct drills, annually and complete a written evaluation of each drill, promptly implementing any correction to the plan.

# Emergency Preparedness

## Proposed Changes § 416.41(a)-(d)

- Must include a facility- and community-based risk assessment, utilizing an all-hazards approach;
- Strategies for addressing emergency events identified by the risk assessment;
- Address type of services ASCs can provide in an emergency; continuity of operations, including delegations of authority and succession plans;
- Process for ensuring cooperation and collaboration with emergency preparedness officials' efforts

# Emergency Preparedness Proposal

## ASCA Concerns

- Community-based requirements
- Develop arrangements with other ASCs and providers to “receive patients in the event of limitations or cessation of operations to ensure continuity of services to ASC patients”
- Track patients & release patient information to family and others in a timely manner

# References

- <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-22.pdf>
- [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf)

A promotional image for the ASCA 2015 event in Orlando. The scene is set at dusk in a resort-like environment. In the foreground, a fire pit with a bright fire is surrounded by modern, light-colored lounge chairs. A bottle of wine and two glasses are on a table. In the background, there is a swimming pool with lounge chairs and umbrellas, palm trees, and a multi-story hotel building. String lights are strung across the scene, adding a warm, festive atmosphere.

# ASCA 2015

ORLANDO : MAY 13-16

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- Go to

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- Enter the five digit code given at the end of the webinar
- Complete the evaluation of the webinar
- Print the continuing education certificate

# Questions??

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