



## Student Manual

# Lesson 1: What is an ASC?

## Learning Objectives



At the conclusion of this lesson, you will be able to:

- Understand the essential characteristics of a Medicare ASC.
- Understand when/how an ASC can share space with temporal separation of services.
- Determine whether a facility qualifies as an ASC.



**What is an ASC?**

Marilyn Dahl  
Director  
Division of Acute Care Services  
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**Learning Objectives**

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**Basic ASC Facts**

- Fast growing industry
- Currently about 5,200 ASCs participate in Medicare
- > 50% growth since 2001, when there were about 3300 ASCs



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**Basic ASC Facts (cont.)**

- Great variation among States in #s of ASCs
  - Variation larger than population size explains
- Nationally, 1 ASC for every 57,855 people
  - But 3 pilot states ranged from 1/every 16,000 people to 1/every 116,500 people
  - ASCs in pilot states with fewer ASCs tended to have more ORs, higher volume, multi-specialty



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**Basic ASC Facts (cont.)**

- 62% of all surgeries in US in 2006 were same-day surgery
  - 61% paid for by Medicare
  - 43% (15 million procedures) took place in ASCs
- Medicare payments to ASCs currently about \$3 B/year



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**Pilot ASC Characteristics**

- 2008 ASC pilot program collected detailed data on 68 randomly selected ASCs in Maryland, North Carolina & Oklahoma
- ASCs come in all sizes and types
  - 18% performed 50 or fewer procedures/month
  - 13% performed 800/month or more



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**Pilot ASC Characteristics (cont.)**

- Multi- vs single specialty:
  - 54% perform one type of surgery
  - 46% perform multiple types
- Number of ORs/Procedure Rooms:
  - 15% have 1
  - 6% have 8
  - Most common #: 2 (35%)



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**Pilot ASC Characteristics (cont.)**

- Approximately 20% of ASCs are deemed by 1 of 4 approved AO's
  - AAAASF
  - AAAHC
  - AOA
  - TJC
- New ASCs more likely to be deemed, since they are Tier IV SA survey priority



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**ASC-HAI ASC Initiative**

- Completed infection control worksheets will provide representative picture of ASCs nationally
- CMS working with vendor to develop easy process to collect completed in FY09-10



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### Medicare ASC Participation

**§416.25 Basic Requirements** (in ASPEN this is the condition-level tag, Q-0001)

- A facility may not participate in Medicare as an ASC unless it meets the definition of an ASC and has in effect a Medicare *supplier* agreement
- Equivalent to a condition-level requirement



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### Medicare ASC Participation (cont.)

- Note ASCs are suppliers, not providers
- Significance: some requirements based on provider agreement rules do not apply, e.g.
  - Office of Civil Rights compliance documentation
  - No specific reg mandating surveyor access to premises & records – must rely upon more cumbersome OIG exclusion



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### Medicare ASC Definition

- 42 CFR 416.2 (in Aspen, this is a standard-level tag, Q-0002) – An ASC:
  - Distinct entity
  - Operates exclusively to provide surgical services
    - to patients not requiring hospitalization
    - expected stay does not exceed 24 hours
  - Has an ASC supplier agreement
  - Complies with ASC CfCs



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### ASC Definition – Distinct Entity

- Many questions come up about this requirement
- Reason – many ASCs operate only part-time & want to use part or all of the same space for other purposes, e.g., physician's office



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### Distinct Entity

- The ASC must be physically separate, clearly distinguishable from any other healthcare facility or physician office
  - Per LSC, must be separated from other operations in the same building by walls with at least 1-hour separation



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### “Temporally Separated”

- CMS considers an ASC to be a distinct entity if it shares its space
  - so long as it is “temporally separated”*
- i.e., same physical premises used by the ASC and another entity, but they are not both open at the same time



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**“Temporally Separated” (cont.)**

- **Shared space temporally separated must be permitted under State law**
  - Federal recognition of ASC’s sharing space under some circumstances does not preempt State laws or regulations that prohibit ASCs from sharing space



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**Sharing Space**

- **On the other hand,**  
**State law or regulations permitting ASCs and another entity to share space and operate concurrently or with overlapping hours are preempted by the Federal definition of an ASC**



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**Adjacent Physician Office**

- Shared non-clinical space - e.g., waiting area, administrative areas, restrooms – may be common. Permitted if:
  - No concurrent or overlapping hours
- LSC requirements for 1-hour separation around the whole ASC still apply



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### Adjacent Physician Office (cont.)

- Medical and administrative records must be maintained separately when administrative space is shared
- ASC records must be:
  - separate from physician office records;
  - secured and not accessible by non-ASC personnel when the ASC is closed



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### Partial Space Sharing

- An ASC may not “rent out” or make available part of its clinical space during ASC business hours
  - E.g., ASC may not let the adjacent physician office use 1 OR or 1 procedure room while the ASC is open



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### Multiple ASCs – Same Space

- **If permitted by State law, 2 or more ASCs may use the same space, so long as they are temporally separated**
  - No overlapping or concurrent hours of operation permitted
    - Does not matter if the other ASC participates in Medicare or not



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### Multiple ASCs – Same Space (cont.)

- **Exceptions** – an ASC may not share space with a Medicare-certified:
  - Hospital or CAH outpatient department, including off-campus ones
  - With a Medicare-participating Independent Diagnostic & Testing Facility



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### Exceptions to Shared Space

- Based on requirements governing hospitals, CAHs, IDTFs, an ASC may **never** share space with one of these



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### ASCs & Provider-Based

- May several ASCs in different locations with common ownership have one CCN number?
  - **No**, an ASC may not be provider-based to any other entity, including another ASC



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**Distinct Entity Enforcement**

- When multiple ASCs use the same space, concurrent recertification surveys may be more efficient
- Whether standard or complaint survey, for deficiencies that are common – e.g., OR emergency equipment missing – each ASC must be cited



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**Distinct Entity Enforcement (cont.)**

- Determine whether State law/regulations permit ASCs to share space
  - If yes, ask the ASC if it shares space, and if so, for evidence that use is not concurrent or overlapping
  - Look for evidence of separate schedules with no overlapping hours



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**Distinct Entity Enforcement (cont.)**

- Verify that ASC medical records are separate and secure when the ASC is not in operation



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**Distinct Entity Enforcement (cont.)**

- ASC complies with definition, except it permits concurrent use of non-clinical space by adjacent physician office or clinic
  - Cite at Standard level – Q-0002
  - But, if this co-mingling results in related deficiencies in medical records, patients' rights, medical staff, nursing staff, etc., citations under these other CfCs might rise to condition-level violation of Q-0001



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**Distinct Entity Enforcement (cont.)**

- ASC shares space, temporally separated, with a hospital, CAH or IDTF:
  - Cite Q-0002 for the first instance (standard);
  - Cite Q-0001 for failure to correct or repeat violations (condition)



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**Distinct Entity Enforcement (cont.)**

- ASC rents out or lets someone else use prep space, OR, procedure room, or recovery room while the ASC is open – cite Q-0001, condition
- 2 or more ASCs operate concurrently in the same space – cite Q-0001, condition



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**Limited Surgical Services Only**

- ASC may provide **only** surgical services
- Includes ancillary services integral to surgery, i.e.,
  - Provided immediately before, during or immediately after surgery
  - E.g. imaging/radiological services used during surgery to guide the surgeon



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**What is “Surgery?”**



Wide range of procedures qualify as surgery

CMS uses modified version of American College of Surgeons definition:

*Surgical procedures are invasive procedures:*

- Performed to structurally alter the body by incision or destruction of tissues

or



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**What is “Surgery?” (cont.)**

- Diagnostic or therapeutic treatment by any instruments causing localized alteration/transposition of live tissue
  - Lasers, ultrasound, ionizing radiation, scalpels, probes, needles



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**What is "Surgery?" (cont.)**

- Tissue can be cut, burned, vaporized, frozen, sutured, probed, manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic or chemical means



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**What is "Surgery?" (cont.)**

- Includes injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs and central nervous system
  - Does **not** include nurses administering subcutaneous, intramuscular or intravenous injections



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**Limited Surgical Services Only**

- ASC surgical services limited to:
  - Performed on patients not requiring hospitalization
  - Services ordinarily not taking >24 hours



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### State Limitations

- If State law/regulations further limit the type of surgical services, the ASC must comply with the State law
- However, if State law permits a broader range of services than Medicare CfCs, the CfCs supercede the State provisions



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### Hospitalization

- Means patient needs supervised recovery period in facility providing hospital inpatient care
- Need for hospitalization depends on both
  - Patient characteristics
  - Nature of the surgery



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### Hospitalization (cont.)

Nature of the surgery:

- Any surgery requiring routine transfer to a hospital afterwards is not appropriate for an ASC



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### Hospitalization (cont.)

Patient characteristics:

- E.g., for a given procedure, a healthy patient <65 might not need hospitalization afterwards, but a 75-year old patient with significant co-morbidities might need hospitalization



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### Hospitalization (cont.)

- ASCs must evaluate both:
  - the procedures it intends to offer; &
  - each patient's likely need for hospitalization



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### “Recovery Centers”

- Some States permit recovery centers that accept ASC post-surgical patients for extended recoveries
  - Don't participate in Medicare; are not licensed hospitals
- Surveyors not expected to determine whether a recovery center is providing hospital inpatient care



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### Services Not > 24 Hours

- ASC cases should not last > 24 hours from admission to discharge



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### Services Not > 24 Hours (cont.)

- Clock starts when the patient moves from the waiting room into another part of ASC, e.g., pre-op prep
  - Patient registration/sign-in time might inappropriately include waiting time
- Clock ends when the patient is discharged and has left the recovery room



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### Services Not > 24 Hours (cont.)

- Generally patient expected to leave both the recovery room and the ASC 15 – 30 minutes after physician signs discharge order
  - Brief stay in waiting room while waiting for ride, escort, etc. permitted after leaving recovery room;
  - It's **not** OK to move the patient to another area in the ASC for fuller recovery after discharge



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### Cases > 24 Hours

- ASC is responsible for continued care of patient until the patient is stable and may be discharged, or is transferred
- Note: If patients are staying in the ASC > 24 hours, under LSC the ASC would be a "healthcare" rather than a "business" occupancy



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### Medicare Beneficiaries

- Medicare payment rules are more restrictive than ASC definition, e.g., generally don't pay for procedures that typically require active medical monitoring and care past midnight
- Surveyors do **not** enforce these payment requirements



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### Enforcement – Cases > 24 Hours

- Admission and discharge times must be documented in the medical record
  - Observe whether ASC is correctly noting times for patients observed during survey
- Review all closed medical records in survey sample to calculate time between admission and discharge



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**Enforcement – Cases > 24 Hours (cont.)**

- A few cases >24 hours ≠ automatic noncompliance
- Individual cases may take longer than expected, due to unforeseen complications



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**Enforcement – Cases > 24 Hours (cont.)**

- Surveyors must review all cases > 24 hours to determine if it was reasonable to expect the case would be <24 hours
  - If Medicare pays for the procedure in an ASC setting, then surveyor may assume it was reasonably expected to last <24 hours
  - However, if the patient had significant comorbidities, the pre-surgical risk assessment and/or QA/PI may have been deficient



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**Enforcement – Not > 24 Hours (cont.)**

- Surveyors not expected to know which surgical procedures Medicare covers in an ASC; ASC can provide evidence of this
- Surveyors may obtain more information on Medicare-covered procedures at:  
[http://www.cms.hhs.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS\\_1404\\_FC\\_ASC\\_AddAA\\_BB\\_DD1\\_DD2\\_EE.zip](http://www.cms.hhs.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS_1404_FC_ASC_AddAA_BB_DD1_DD2_EE.zip)



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**Enforcement – Cases > 24 Hours (cont.)**

- For procedures not covered by Medicare in ASCs, ask for evidence why it was reasonable to expect the case would be <24 hours
  - E.g., other ASC cases involving similar procedure and patients



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**Enforcement – Not > 24 Hours (cont.)**

- Cite ASCs with more than a few cases > 24 hours that lack good rationale for expecting those cases to be <24 hours at both the standard (Q-0002) and condition (Q-0001) level



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**ASC Definition**

- Has a Medicare ASC supplier agreement
  - Unlike hospitals, where Medicare recognizes non-participating hospitals and pays them for certain emergency services, an “ambulatory surgical center,” refers only to an entity participating in Medicare as an ASC



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**ASC Definition (cont.)**

- Complies with Subparts B & C of Part 416
  - Subpart B: ASC supplier agreement requirements
    - Enforcement generally follows process at SOM Section 3030 for provider agreements
  - Subpart C: ASC Conditions for Coverage



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**Summary**

An ASC must:

- Be a distinct entity
- Provide only surgical services
  - For people not needing hospitalization
  - Up to 24 hours
- Have an ASC Medicare agreement
- Comply with ASC agreement requirements & CfCs



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**Summary (cont.)**

- Serious violations of the distinctness, sole surgical services and < 24 hours/case requirements should be cited at "condition" level, i.e., Q-0001, ASC Basic Requirements



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**Questions?**

Thank you!



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## Student Manual

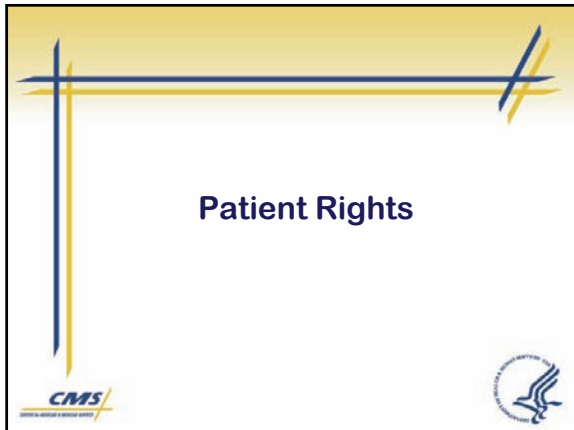
# Lesson 2: Patient Rights

### Learning Objectives



At the conclusion of this lesson, you will be able to:

- Identify the components that comprise patient rights.
- Understand the grievance process.
- Understand and assess compliance with privacy and safety requirements, including confidentiality of patient records.





**Patient Rights**

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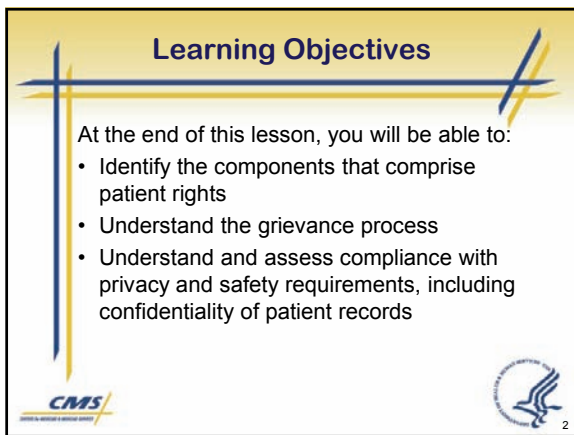
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**Learning Objectives**

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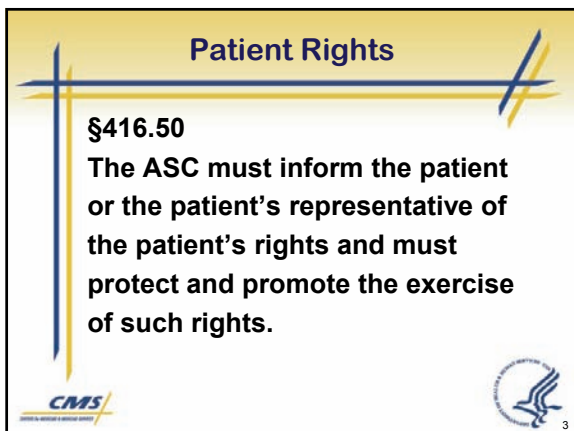
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**Patient Rights**

**§416.50**  
**The ASC must inform the patient or the patient's representative of the patient's rights and must protect and promote the exercise of such rights.**

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**Notice of Rights**

**§416.50(a)(1)**  
The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.



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**Notice of Rights (cont.)**

**§416.50(a)(1)** In addition, the ASC must –

(i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of Medicare Beneficiary Ombudsman.



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**Notice of Rights (cont.)**

**§416.50(a)(1)** In addition, the ASC must –

(ii) The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.



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### Patients' Rights

- Patients' rights include:
  - Notification
  - Physician financial interests/ownership
  - Advance directives
  - Grievances
  - Exercise of rights
  - Privacy and safety
  - Confidentiality of clinical records
- The ASC must be proactive in protecting each patient's rights



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### Notification

- Each ASC must inform the patient or the patient's representative of the patient's rights
- The ASC must protect and promote the exercise of the patient's rights



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### Assessing Compliance

- Patient rights condition should be coordinated by one surveyor
  - All surveyors should assess compliance with the Patient Rights requirements
- Observe during case tracer how the ASC's actions protect and promote patient's exercise of rights



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### Notice of Rights

- Must be verbal and written
- Provided to patient or patient's rep
- In advance of the date of procedure
- In a language and manner patient or patient's rep understands



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### Verbal and Written Notification

- Verbally advise patient at the time appointment is scheduled
- Follow-up with written notification
  - Delivered in a manner that reasonably ensures receipt
    - Email is okay



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### Written Notification

- No specific format or wording
- Must:
  - Address all rights required under Condition and any State or other Federal law
  - Be provided and explained in a language and manner patient or patient's rep understands
    - Not required to be in every language
    - May need to use translation services
    - See 73 FR 68717-68718



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### Notification Question

- Is the ASC required to obtain the patient's signature for the patient rights information?
- Although there is no signature requirement, the ASC must be able to prove the required materials were mailed to the patient in advance of the procedure. Obtaining a signature indicating the patient received the materials upon their admission would be one example, but not necessarily a requirement



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### In Advance of the Date

- Written notification must be provided in advance of the date of the procedure
- **Unless**
  - Referral for surgery is made on the same date
- And
  - Referring physician indicates
    - Medically necessary to have surgery on same day
    - ASC is the suitable setting
  - Must be in writing
  - Surgery on same day as scheduled should be rare



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### In Advance of the Date Question

- If a patient has a procedure scheduled on May 3<sup>rd</sup> and another procedure scheduled on May 15<sup>th</sup>, does the facility need to issue patient rights notification forms for each procedure?
- If the facility provides notification indicating that the notification is in reference to both procedures, i.e., states the dates of both scheduled procedures, then the patient rights requirements have been met for both procedures with the one notice



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**In Advance of the Date Question (cont.)**

- Suppose the dates of the second procedure are unknown?
- If the date of the second procedure is unknown, then the facility will have to issue new patient rights forms when the date for the second procedure is known



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**Assessing Compliance – Patient Rights**

- Review ASC’s policies and procedures regarding notification of patients
  - Consistent with regulatory requirements?
- Review written notification provided to patients
  - Does it address all patient’s rights
  - Applicable State law requirements? Are they addressed?



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**Assessing Compliance – Samples**

- Review a sample of records
  - Determine if ASC documents provision of written notification
  - Assess frequency of same day surgeries
    - Documentation that patient was referred on same day
    - Documentation that ASC was suitable setting
    - Documentation that same day surgery was medically necessary
  - Determine if written materials available for patients with limited English proficiency



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### Assessing Compliance – Patient Rights

- Observe patient/staff interaction
- Interview staff
  - Are they aware of policies for providing notice?
  - How does the ASC communicate to patients needing assistive devices or translation services?



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### Assessing Compliance – Case Tracer

- During case tracer, observe:
  - Whether the ASC informed patients of their rights
  - What was communicated
  - How the information was communicated
  - At what point in the process was the information communicated



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### Notice of Rights

- Must be posted in place in facility likely to be noticed by patients or reps waiting for treatment
- Must include:
  - Name, address, telephone for State agency rep to whom patients can report complaints
  - Web site for the Office of the Medicare Beneficiary Ombudsman
    - [www.medicare.gov/ombudsman/resources.asp](http://www.medicare.gov/ombudsman/resources.asp)



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### Assessing Compliance

- Observe to see if notice of patient rights is posted
  - Waiting rooms, recovery rooms, common areas
  - At least one notice
- Observe to see if the notice contains the required information



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### Financial Interest or Ownership

Must disclose physician financial interest or ownership

- In accordance with 42 CFR 420
- Must be in writing
- Furnished in advance of the date of procedure



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### Intent of Disclosure

Assist the patient in making an informed decision about his or her care by making the patient, or the patient's rep, aware when a physician who refers their patient to the ASC for procedures, or physician who performs procedures in an ASC also have an ownership or financial interest in the ASC



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**Physician Ownership/Interest Question**

- Is the ASC required to provide patients with a complete list of physicians possessing ownership/financial interests or should the ASC only provide ownership/interest information on the patient's treating physician?
  - The patient should be provided with a complete list of physician owners or investors, not just the treating physician.
  - Providing the patient with only notification that the facility is physician owned is not sufficient



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**42 CFR 420.201**

- A physician owner or investor is, for example, an individual who has an ownership interest totaling 5 percent or more in a disclosing entity, an individual who has an indirect ownership interest equal to 5 percent or more in a disclosing entity, or an individual who has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity



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**Assessing Compliance – Physician Ownership/Interest**

- Ask if ASC has reported to the Medicare program whether it has any physicians with ownership/financial interests
- If no, the ASC has no disclosure requirements and no further investigation is needed



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**Assessing Compliance – Physician Ownership/Interest (cont.)**

- If yes:
  - Does the ASC have policies and procedures regarding the required disclosures?
  - Do the P&Ps comply with the requirements?
- Interview staff
  - Assess their knowledge/understanding of the requirements
- Interview patient
  - Aware of physician owners/investors
  - Did they receive a written notice prior to the procedure?



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**Advance Directives**

**§416.50(a)(2)**  
The ASC must comply with the following requirements:

(i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with 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



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**Advance Directives (cont.)**

**§416.50(a)(2) (cont.)**

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

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



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**Advance Directives (cont.)**

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.



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**Advance Directives (cont.)**

- ASC must disseminate:
  - Policies regarding implementation of advance directives
  - Description of applicable State health and safety laws
  - Official State advance directive forms
    - If applicable
  - Information on patient's right to make informed decisions regarding the patient's care



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**In Advance of the Date**

- Written notification must be provided in advance of the date of the procedure
- **Unless:**
  - Referral for surgery is made on the same date and
  - Referring physician indicates
    - Medically necessary to have surgery on same day
    - ASC is the suitable setting
  - Must be in writing
  - Surgery on same day as scheduled should be rare



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### Advance Directive

- Clear statement of any limitations on basis of conscience
- In advance of the date of surgery, must provide notice of patient's rights regarding advance directives, including patient's right to accept or refuse medical care and the patient's right to formulate an advance directive



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### Documentation

- ASC must document in a **prominent part** of the medical record whether or not the patient has executed an advance directive
- Must not condition provision of care or otherwise discriminate based on whether or not patient has an advance directive
- If patient is transferred, ASC must ensure copy of advance directive is provided with the medical record



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### Assessing Compliance – Advance Directives

- Review ASC's policies and procedures
  - Conform to regulatory requirements
- Review ASC's written notice of the advance directive policies and applicable State law
- ASC must educate staff on its policies and procedures



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**Assessing Compliance – Advance Directives (cont.)**

Sample medical records

- Evidence that information was provided to patient in advance of date of procedure
- Same day surgery exception requirements
  - If applicable
- Information must be prominently displayed



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**Grievances**

**§416.50(a)(3)**

(i) 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

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



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**Grievances (cont.)**

**§416.50 (a)(3)**

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

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

(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.



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**Grievances (cont.)**

**§416.50(a)(3)**  
(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.  
(vii) The ASC must document how the grievance was addressed, as well as provide the patient 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.



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**What is a Grievance?**

- A formal or informal written or verbal complaint filed by a patient regarding a patient's care when:
  - A patient issue **is not** or cannot be resolved promptly [on the spot] by staff present
- **Does not include:**
  - A complaint presented to staff and resolved at that time
  - Billing issues



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**Grievances (cont.)**

- **Neglect:** failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness
- **Abuse:** willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish



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### Forms of Grievances

- Written (always)
- Verbal
- Satisfaction surveys (ID vs. no ID)
- Post-discharge phone calls
- Request to handle
- Request a response from the ASC



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### Grievance Process

- Must establish a clearly explained procedure for the submission of a patient's written or verbal grievances
- Specify time frames for review, and must provide a written response to each patient
- Document how grievance was addressed
- May use **additional** methods to resolve grievance
  - Meeting with patient's family
- Incorporate grievance process into QAPI program



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### Grievances (cont.)

- Grievances alleging mistreatment, neglect, or abuse **must** be reported:
  - Immediately (as soon as possible)
  - At least on the same day
  - By staff to ASC official with authority to address
- Must be investigated as soon as possible
- If confirmed, obligated to report to appropriate local or State authority or both



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### Grievance Resolution

- The ASC **must** provide the patient with written notice:
  - ASC decision
  - ASC contact person
  - Steps taken to investigate the grievance
  - Investigation results
  - Completion date
- Written response **always** required for every "grievance"



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### Assessing Compliance – Grievances

- Written policy addressing grievance process, including grievances alleging mistreatment, neglect, or other serious harm
  - Documentation
  - Submission
  - Investigation
  - Resolution



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### Assessing Compliance – Grievances (cont.)

- Ask ASC how many grievances were received during past year
- Review a sample of grievance files
  - Properly documented
  - Handled in accordance with policy and regulatory requirements



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**Assessing Compliance – Grievances (cont.)**

- Interview individual authorized to handle grievances
- Interview staff:
  - Aware of grievance policies
    - Complaint handled on spot vs. grievance
  - Education on how to handle grievances and allegations
  - Reporting
    - Appropriate person
    - Timeframe



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**Assessing Compliance – Grievances (cont.)**

- Interview patients/representatives:
  - How to file a grievance
  - Who to contact if they have a complaint/grievance



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**Exercise of Rights and Respect for Property and Person**

**§416.50(b)**

**(1) The patient has the right to –**

- (i) Exercise his or her rights without being subjected to discrimination or reprisal.**
- (ii) Voice grievances regarding treatment or care that is (or fails to be) furnished.**
- (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.**



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### Exercise Rights

- If patient exercises his rights, ASC may **not**:
  - Take punitive action
  - Discriminate
- Must be reflected in patient rights policies and procedures



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### Voice Grievances

- Patient may file grievance regarding treatment furnished or failure to furnish
- Grievance may be filed:
  - Verbally or in writing
  - Before, on, or after date of procedure
- No limitation on when patient may submit grievance
  - Substantial passage of time may hinder ASC's ability to investigate



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### Informed Decisions

- Patient or patient's representative is given information needed in order to make informed decisions regarding care
  - Patient has information about health status, diagnosis, and prognosis
  - Includes patient's participation in the development of plan of care
    - Consent to or refusal of interventions
    - Planning for care after discharge
- Provided in a manner that can be understood by patient



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### Informed Consent

- Must be obtained prior to start of procedure
- Documented in medical record
  - See §416.41(b)(7)



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### Informed Consent Policy

- Who may obtain informed consent
- Circumstances when representative may give informed consent
- Content of form and instructions
- Process to obtain and properly execute
- Incorporation into medical record



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### Informed Consent Process

- Description of proposed surgery
- Indications
- Material risks and benefits
- Treatment alternatives
- Consequences of declining therapies
- Staff
  - If practitioner other than physician



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### Assessing Compliance – Exercise of Rights

- Review ASC policies
  - Clear that patient may exercise rights without fear of reprisal
- Interview staff
  - Aware of patient's right to file grievance
  - Aware that patients may not be treated differently if patient files a grievance



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### Assessing Compliance – Informed Consent

- Review informed consent policy
  - Complies with regulatory requirements
- Select sample of medical records
  - Presence of informed consent
  - Documentation it was given prior to surgery (and prior to pre-op anesthesia)
- During case tracer
  - Executed prior to surgery (and pre-op anesthesia)
  - If not, observe and document when it was obtained



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### Exercise of Rights and Respect for Property and Person

**§416.50(b)**  
**(2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.**  
**(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.**



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### Legal Representative

- Determination of incompetence
  - Person appointed under State law to act on behalf may exercise all rights afforded to ASC patient
- Delegation of rights
  - Wishes respected to the degree permitted by law and to the maximum extent practicable



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### Assessing Compliance – Delegation of Rights

Verify:

- Policy addressing exercise of rights for patient judged legally incompetent
- Policy addressing delegation of exercise of rights



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### Privacy and Safety

**§416.50(c)**  
The patient has the right to –

- (1) Personal privacy
- (2) Receive care in a safe setting
- (3) Be free from all forms of abuse or harassment



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### Personal Privacy

- At a minimum:
  - Privacy during hygiene activities, provision of care/treatments, while clinical care issues are discussed and when requested (as appropriate)
  - Limiting disclosure of patient information
  - Including patient's presence in the facility



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### Personal Privacy (cont.)

- Circumstances may require the ASC to inform the patient's significant others of the patient's situation, when the patient cannot do so, such as, when an emergency medical condition requires a transfer to a hospital
  - Patient should have previously provided who to contact in such a situation
  - Minimum information, such as "Mr Smith had an emergency medical condition was transferred to City Hospital ED at 10AM"



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### Privacy Considerations

- No audio/video recording without patient's consent
- Does not apply to monitoring/taping of public areas for security
  - Stairwells
  - Public waiting areas



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### Safe Setting

- Follow current standards of practice
  - Environmental safety
  - Infection control
  - Security and personal safety
- Also include emotional safety
  - Respect
  - Dignity
  - Comfort



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### Assessing Compliance – Safe Setting

- Review/analyze incident and accident reports
- Review documentation
  - Safety, infection control, security
  - Identification, evaluation and correction
- Observe environment
  - Curtail unwanted visitors
  - Contaminated materials
- Interview patients and staff



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### Abuse or Neglect

- Abuse: willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical, pain or mental anguish
- Neglect: failure to provide goods & services necessary to avoid physical harm, mental anguish or mental illness
  - Neglect is considered a form of abuse



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**Suggested Components:  
Abuse Prevention Program**

1. Prevent
2. Identify
3. Train
4. Investigate
5. Respond



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**Assessing Compliance –  
Abuse & Neglect**

- What systems is in place to protect, whether from staff, visitors, or other persons
  - Staffing
  - Written procedures
- Interview staff – what can staff tell you about the process, define abuse, recent investigations, State requirements?



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**Confidentiality of  
Patient Records**

**§416.50(d)**  
**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.**



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### HIPAA

- Health Insurance Portability & Accountability Act of 1996
  - Standards for health care providers/suppliers
  - Covered electronic transactions
    - Privacy of protected health information
    - Security of electronic protected health information
  - Privacy Rule
    - Protects individually identifiable health information



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### Privacy Rule

- Privacy rule permits ASCs to create own privacy procedures
- Requirements may be found at:  
[www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html](http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html)



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### Security Rule

- Establishes standards for the security of health information
  - Series of administrative, technical, and physical security standards
- Only applies to electronic protected health information
- [www.cms.hhs.gov/SecurityStandard/](http://www.cms.hhs.gov/SecurityStandard/)



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### Confidentiality of Records

- Focus on ASC's efforts to protect confidentiality of clinical records
- Records may be viewed
  - When necessary
  - By individuals participating in some aspect of patient care
- Applies to central storage of closed records and open records used throughout facility



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### Assessing Compliance – Confidentiality of Records

- Policies in place to prevent release or disclosure of individually identified patient information
- Observe locations of patient information
- Security measures



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### Summary

- Patient rights include:
  - Notification
  - Physician financial interests/ownership
  - Advance directives
  - Grievances
  - Exercise of rights
  - Privacy and safety
  - Confidentiality of clinical records



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**Summary (cont.)**

- ASCs are expected to inform patients of their rights, in a manner understood by the patient, in advance of the date of procedure
  - Same day surgery exception



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**Summary (cont.)**

- Patients have a right to:
  - Privacy
  - Safety
  - Freedom from abuse or harassment
- Patients also have a right to the confidentiality of clinical records



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**Questions?**

**Thank you!**



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## Student Manual

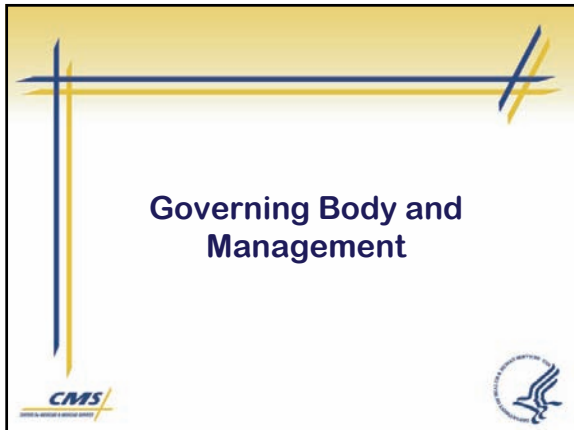
# Lesson 3: Governing Body and Management

## Learning Objectives

At the conclusion of this lesson, you will be able to:


- Understand the roles and responsibilities of the governing body.
- Be able to effectively evaluate an ASC's disaster preparedness plan.
- Understand the procedure for the transfer of a patient to a hospital.





**Governing Body and Management**

CMS  
CENTERS FOR MEDICARE & MEDICAID SERVICES



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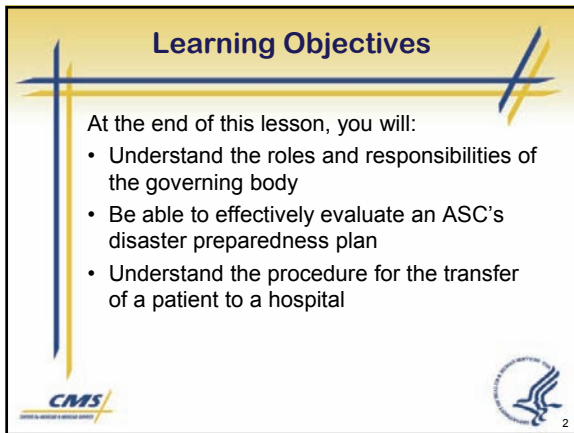
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CMS  
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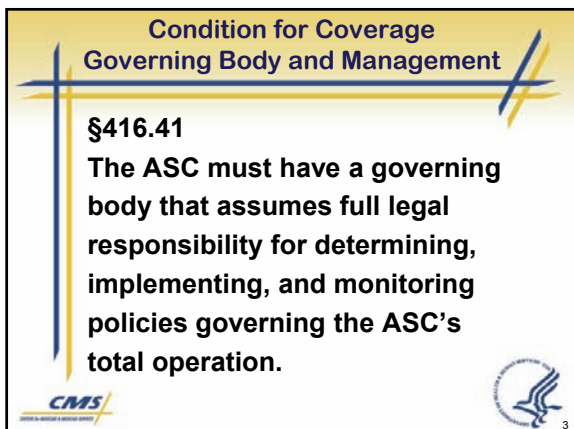
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**Condition for Coverage  
Governing Body and Management**

**§416.41**

**The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation.**

CMS  
CENTERS FOR MEDICARE & MEDICAID SERVICES



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**Condition for Coverage**  
**Governing Body and Management (cont.)**

**§416.41**  
The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops and maintains a disaster preparedness plan.



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**Governing Body**

- Must be effective!
- Must get things done!
- Other GB requirements found in:
  - Patient rights CfC
  - QAPI CfC
  - Medical Staff CfC



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**Key Changes in Regulation**

- There are two key changes in the Governing Body requirements:
  - An explicit statement of the governing body's responsibility for the Quality Assessment/Performance Improvement program
  - A requirement for disaster preparedness plan



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**Governing Body**

Responsibilities:

- Establishing ASC's policies
- Ensuring that the policies are implemented
- Monitoring internal compliance with the policies
- Assessing the policies periodically to determine if revisions are needed



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**Governing Body (cont.)**

Specifically, the governing body's responsibilities include:

- Adopting formal policies and procedures that govern **all** operations within the ASC
- Direct oversight and accountability of the ASC's QAPI program
- Ensuring the quality of the ASC's healthcare services
- Ensuring that the ASC provides a safe environment for care; and
- Developing and maintaining a disaster preparedness plan



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**Safe Environment**

- Governing body, "ensures that the facility policies and programs are administered so as to provide quality healthcare in a **safe environment**".
- A powerful requirement
- "A safe environment" has the same meanings as "a safe setting" in the Patients' Right CFC



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**Safe Environment – Citation**

- If ASC policies or practices, or situations demonstrate that the ASC is in non-compliance with the “safe setting” requirement in the Patients’ Rights CoP
- If the situation results in Condition level non-compliance due to an “unsafe setting,” then the resulting non-compliance with the requirement for a “safe environment” should likely result in a citation of the governing body CfC at condition level



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**Governing Body (cont.)**

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



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**Delegation of Responsibilities**

- Governing body may delegate day-to-day operational responsibilities
  - To administrative, medical or other personnel
  - Retains ultimate responsibility
    - for overall operations and
    - Quality of services
  - Delegation must be documented in writing



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**QAPI – Citations**

**When QAPI citations are made related to §416.43, particularly Standard (e) (Governing body responsibilities), citation of §416.41 should also be considered.**



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**Condition-level Deficiencies**

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



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**Governing Body Question**

Does an annual evaluation of the ASC's services need to be submitted to the governing body?

Evaluation of services is required to be ongoing, not just once a year. Distinct performance improvement projects are required to be conducted each year. In order for the governing body to accomplish its responsibilities, it should receive regular feedback on the progress of the ASC's programs as well as any changes that might be required.



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**Assessing Compliance – Governing Body**

- Request from leadership information about the governing body
  - Who constitutes the ASC’s governing body
    - See CMS Form 855B for identification of individuals with ownership interest or management control



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**Assessing Compliance – Governing Body (cont.)**

- Also request from leadership, a copy of the organization chart of the ASC management – who performs the following:
  - Human resources
  - Medical staff credentialing/granting of privileges
  - Management of surgical svcs., nursing svcs., pharmaceutical svcs., lab/radiologic svcs, physical plant
  - Medical records maintenance
  - Infection control
  - QAPI



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**Assessing Compliance – Governing Body (cont.)**

- Has the governing body delegated operational responsibility to a manager?
  - Request written documentation of delegation



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**Assessing Compliance – Governing Body (cont.)**

- Ask leadership about the governing body meeting:
  - Frequency of meetings
  - Agenda items
  - Meeting minutes



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**Assessing Compliance – Governing Body (cont.)**

- Review minutes or other evidence to ensure:
  - Policies and procedures have been formally adopted
  - Policies are implemented
  - Monitoring internal compliance/reassessment of policies
    - Data collected and submitted related to specific policies
  - Ongoing oversight of and accountability of QAPI program
    - See §416.43



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**Contract Services**

**§416.41(a)**  
**When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner**



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**Contract Services (cont.)**

ASC may contract with a third party for the provision of ASC services, including environment

- This is a common occurrence
- Governing body still responsible for oversight of the delivery of such services
- Must ensure contract services are provided safely and effectively
- Contract services must be included in the QAPI program



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**Contract Services (cont.)**

- If ASC contracts:
  - For cleaning of ASC, governing body still responsible for sanitary condition of ASC
  - For nursing services, ASC responsible for direction of staff, ensuring licensure, training, orientation to duties of nursing staff
  - For anesthesia services, ASC responsible for reviewing credentials and granting privileges
  - For receptionist or medical records services, ASC must ensure contractor meets patient rights and medical records CfCs



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**Assessing Compliance – Contract Services**

- Ask ASC for a complete list of its currently contracted services
- Ask ASC how it assesses the safety and effectiveness of the contracted services
  - How such services are incorporated into its QAPI program



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**Assessing Compliance – Contract Services (cont.)**

Select a sample of contractors from the list

- Review documentation of the ASC's most recent assessment of each



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**Assessing Compliance – Contract Services (cont.)**

- Review the personnel files of each contract personnel to determine:
  - Credentials
  - Privileges
  - Evidence of training
  - Evidence of periodic evaluation
- Example:
  - Ensure that all contracted nurses are properly licensed and oriented to their duties
  - Ensure anesthesiologists and anesthetists possess the proper credentials



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**Assessing Compliance – Contract Services (cont.)**

- If the ASC shares space with other entities:
  - Ask ASC if it contracts or has some formalized arrangement with the other entities when the ASC is in operation
  - May not share space with an IDTF
- If the ASC utilizes services of employees of other entities while it is in service and has no contract or formal documentation of an arrangement, the governing body has failed to exercise its responsibility for the administration of the ASC's program



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**Assessing Compliance – Contract Services (cont.)**

- Ask management about the process for correcting deficiencies in contracted services
  - Has the facility identified deficiencies?
    - If so, what corrective action was taken?
- Ask facility to provide documentation of such cases



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**Hospitalization**

**§416.41(b)**  
**(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.**



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**Hospitalization (cont.)**

**§416.41(b)**  
**(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 42 CFR 482.2.**



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**Hospitalization (cont.)**

**§416.41(b)**  
**(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.**



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**Transfer of Patient**

- ASC must be able to transfer patient when:
  - Patient experiences a medical emergency that the ASC is not capable of handling or
  - Which requires emergency care extending well beyond the 24-hour timeframe for ASC cases
    - Immediately
    - To a local hospital
- See §416.44(c) & (d) – emergency care capabilities each ASC must have



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**Immediate Transfer Procedure**

- An effective procedure for immediate emergency transfers must include:
  - Written policies and procedures that address circumstances warranting emergency transfer
    - Who makes the decision
    - Required documentation
    - Procedure for accomplishing the transfer safely and expeditiously
  - Provision of emergency care and initial stabilizing treatment within the ASC's capabilities until patient is transferred



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**Immediate Transfer Procedure (cont.)**

- Arrangement for immediate emergency transport of patient
  - ASC may contact 911 to arrange emergency transport
  - Unless State license require additional arrangements
- There must be evidence that staff is aware of and can implement the policy immediately upon development of a medical emergency



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**Transfer to a Local Hospital**

- ASC is required to transfer patient who require emergency transfer to:
  - Nearest local Medicare-participating hospital OR
  - Local, non-Medicare-participating hospitals
    - Meets requirements for emergency services by the Medicare program
      - 42 CFR 482.2



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**Emergency Services by Nonparticipating Hospitals**

**§482.2**

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if –

- (1) The services are emergency services; and
- (2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act.



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**Emergency Services by Nonparticipating Hospitals (cont.)**

- Section 1861(e)(1) through (5) and (7) of the Act provide the definition of a hospital
  - Most non-participating hospitals in the US consist of Military and VA hospitals



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**Transfer to a Local Hospital (cont.)**

- “Local” hospital means the ASC is to consider the most appropriate facility to which the ASC will transport its patients in the event of an emergency
  - More distant hospital may meet definition
    - Closest hospital can not accommodate patient population OR
    - Closest hospital can not accommodate predominant medical emergencies associated with the type of surgeries performed by the ASC



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**Transfer to a Local Hospital (cont.)**

- A State-specific definition of a “local” hospital for ASC transfer purposes does not override the Medicare requirement to use the hospital nearest to the ASC with the appropriate capabilities
- An ASC is required to transfer its emergency cases to the nearest, most appropriate local hospital
  - Delay in transfer could affect patient’s health



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### Transfer Agreement or Hospital Privileges

- ASC must:
  - Have a written transfer agreement
    - That is in force
    - With a local, Medicare participating hospital or a local nonparticipating hospital that meets requirements for payment for emergency services
  - OR
  - Ensure that every physician performing surgery
    - Has admitting privileges at a local, Medicare participating hospital or a local non-participating hospital that meets requirements for payment for emergency services



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### Transfer Agreement

- Written agreement
- Signed by authorized representatives of the ASC and hospital
- Hospital agrees to accept transfer of ASC's patients who need inpatient hospital care, including emergency care



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### Transfer Agreement (cont.)

- Establishes the responsibilities of each party to the agreement
- May have an expiration date
- May have terms stating it remains in effect until and unless one of the parties terminates the agreement



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### Hospital Privileges

- If there is no transfer agreement, ASC must maintain documentation of the current admitting privileges of all physicians who perform surgery at the ASC at local hospitals
  - Must satisfy requirements in §416.41(b)(2)
- Even when the hospital has a transfer agreement, it remains a good practice for the ASC to maintain documentation of privileges



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### Hospital Privileges (cont.)

- More than one local hospital that meets requirement for local transfer destination
  - May satisfy requirement if its operating physicians each have admitting privileges at one of the eligible hospitals
  - All physicians do not have to have privileges at the same hospital



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### Hospital Privileges (cont.)

- Physician who performs surgery on the patient requiring emergency transfer
  - Expected to arrange admission of patient
  - Unless compelling clinical reason to transfer to a different local hospital where physician does not have admitting privileges



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### Hospital Acceptance of Transfer

- Existence of a transfer agreement or possession of privileges is not a guarantee that the hospital will accept a specific transfer
  - May lack capacity to provide required service
- ASC should have alternative plans to address such contingencies



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### Emergency Medical Treatment and Labor Act (EMTALA)

- If local hospital is a Medicare-participating hospital and, it has a dedicated emergency department, it is obligated under EMTALA to provide a medical screening exam and stabilizing treatment once patient arrives on hospital's property
- Relying on EMTALA obligations does not satisfy an ASC's transfer requirements



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### Hospital Transfer

- ASC may call 911 to arrange emergency transport
- ASC must take steps to arrange the admission of the patient to a local hospital



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**Assessing Compliance – Hospitalization**

- Review the ASC’s policy and procedures for emergency transfer of patients
- Review document to determine if it addresses essential elements:
  - An immediate transfer procedure
  - Transfer agreement
  - Hospital privileges



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**Assessing Compliance – Hospitalization (cont.)**

- Ask the ASC if it has a transfer agreement with an eligible local hospital
  - Ask to see the agreement
  - Look for the expiration date
  - If no expiration date, ask if the agreement has been terminated by either party
- If in doubt about the agreement, contact the local hospital to see it has a current transfer agreement with the ASC



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**Assessing Compliance – Hospitalization (cont.)**

- Interview staff
  - How would they handle a medical emergency of a patient that could not be managed in the ASC?
  - Do they know the policies and procedures for emergency transfer?
  - Do they know how to arrange an emergency transport?



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**Assessing Compliance – Hospitalization (cont.)**

- If the ASC does not transfer patients to the closest eligible hospital
  - Ask ASC to explain why
- If there is no transfer agreement, ask for documentation that each physician performing surgery in the ASC has admitting privileges at an eligible local hospital
  - Ask ASC how it verifies the privileging information is current



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**Assessing Compliance – Hospitalization (cont.)**

- Determine if the ASC has had any emergency transfers in the last 12 months
  - Review medical records to determine if patient was transferred to a hospital meeting the regulatory requirements for a local hospital
  - Did the ASC have a transfer agreement or a physician with admitting privileges at each hospital a patient was transferred to
  - Does medical record indicate the steps the ASC took to arrange the transfer, beyond calling 911?



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**Disaster Preparedness**

**§416.41(c)**

**(1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff, and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.**



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**Disaster Preparedness (cont.)**

§416.41(c)

- (2) The ASC coordinates the plan with State and local authorities, as appropriate.
- (3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.



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**Disaster Preparedness Plan**

- ASC should have a plan to care for patients, staff, and others
  - On the premises
  - In the event of a major disruption
    - Fire
    - Flood
    - Mass release of a biochemical hazard
    - Failure of the water supply
- Governing body is responsible for development of this plan



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**Disaster Preparedness Plan (cont.)**

- In developing plan, consider:
  - Hazard identification: include any potential hazards that could likely affect the facility directly and indirectly
  - Hazard mitigation: activities taken to eliminate or reduce the probability of the event, reduce event's severity, prior to or following a disaster
    - Address care of patients pre-op, during, and post-op
    - Precede any imminent or post-impact timeframe
    - Such efforts will reduce staff and patient vulnerability to hazards



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**Disaster Preparedness Plan (cont.)**

- In developing plan, also consider:
  - Preparedness: developing a plan on meeting needs of patients, staff, others if essential services break down
    - Analysis of ASC's ability to continue care
    - Includes training staff on their role
    - Testing plan and revising as needed
  - Response: activities taken immediately before, during and after disaster
  - Recovery: activities taken during and after ASC's response



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**Plan Coordination**

- Must coordinate with State and local authorities
  - Address threats that extend beyond premise of ASC
  - Address threats within ASC that require response from community agency
- Assists in overall emergency management planning efforts within community
- Ascertain assets and capabilities of during an emergency



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**Plan Coordination (cont.)**

- ASC's plan does not have to be integrated into State and local emergency plans for threats that extend beyond ASC's premise
  - Key phase: "as appropriate"
- ASC must document efforts to communicate with State and local emergency preparedness officials regarding potential coordination



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### Testing, Evaluating and Updating Plan

- ASC must conduct a drill
  - Test plan's effectiveness
  - At least once a year
  - Conducted in concert with State or local authorities would qualify
  - Test at least a significant portion of plan
  - Fire drill does not qualify



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### Testing, Evaluating and Updating Plan (cont.)

- Prepare written evaluation of annual drill
  - Identify problems
  - Develop methods to address problems
  - Update disaster preparedness plan to reflect lessons learned from drill and any changes identified in evaluation



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### Assessing Compliance – Disaster Preparedness Plan

- Request copy of emergency preparedness plan
- Ask ASC leadership
  - to summarize plan
  - how staff are informed of plan, including roles and responsibilities
- Interview ASC staff, including physicians
  - Determine if staff are aware of plan and contents
  - Determine if they can summarize their role and responsibility



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**Assessing Compliance – Disaster Preparedness Plan (cont.)**

- Ask for evidence of coordination with State or local emergency management agencies
- Ask for documentation of annual drill
  - Ask leadership how drill was conducted
  - Ask what features of the plan it is designed to test
  - Ask staff if they have participated in a drill to test emergency preparedness



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**Assessing Compliance – Disaster Preparedness Plan (cont.)**

- Ask to see written evaluation of drill
  - Determine if evaluation reviews drill in detail
  - Does evaluation assess whether tested plan features performed as expected
  - If there were problems, does evaluation indicate changes needed
  - If changes were needed, verify plan was revised and changes implemented



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**Summary**

- Governing Body
  - Full, legal responsibility for policies governing total operation
  - Responsibility may be delegated; must be in writing
- If ASC receives services from outside contractor
  - Must assure safety and effectiveness of services
  - Must be included in QAPI program



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**Summary (cont.)**

- ASC must have a written transfer agreement or physicians must have admitting privileges
  - At local Medicare participating or local non-participating hospital meeting requirements for payment for emergency services under §482.2



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**Summary (cont.)**

- ASC must have a written disaster preparedness plan
- Must coordinate plan with State and local authorities
  - “as appropriate”
- Must conduct drill to test plan’s effectiveness
  - At least annually
- Must complete written evaluation of drill and promptly implement any corrections to plan



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**Questions?**

**Thank you!**



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