

Your Responsibilities as the Medical
Director of an ASC – CMS Legal
Requirements

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Summit

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**SOCIETY FOR
SAMBA** ULATORY
ANESTHESIA

Outpatient • Office Based • Non-Operating Room

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Disclosures

- Am an attorney in private practice,
- I have no other financial interests to disclose

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Objectives

- Review multiple sources of a Medical Director's obligations
- Review areas of Medical Director responsibility
- Review areas of exposure for a Medical Director
- Suggest strategies to enhance a Medical Director's ability to be successful in carrying out his/her obligations

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ASC Medical Director
Sources for Areas of Responsibility

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Sources of Obligations

- ASC governing documents
- Services agreement – either
 - Part of anesthesiology services agreement or
 - Separate medical director agreement
- External legal requirements, including:
 - State licensing requirements
 - CMS Conditions for Coverage (regs & guidelines)
- Accreditation requirements

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Sources of Obligations

- Because obligations may derive from contracts, they may differ from one ASC to another
 - There may be a Medical Director of the ASC *and* a Medical Director of Anesthesia
 - Important to understand the duties of multiple Medical Directors (if there are multiple ones)

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CMS Requirements



- Medical Director obligations stem from CMS requirements
- Source documents:
 - CMS Regulations: 42 CFR. (Code of Federal Regulations) Part 416: Ambulatory Surgical Services
 - Available at <https://www.ecfr.gov/cgi-bin/text-idx?SID=10312e2866e2c1e86b6804e2e36667b428&mc=true&nnode=pt42.3.416&rgn=div5>
 - CMS Policy: *State Operations Manual*, Pub. No. 100-07, Appendix I: Guidance for Surveyors: Ambulatory Surgical Centers
 - Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf

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Your Responsibilities as an ASC Medical Director



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Areas of Responsibility



- Importantly: CMS lays obligations for ASCs at the hand of the ASC
 - Not any Medical Director
- The duties we will review are those of the ASC – but typically are delegated to the Medical Director

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Areas of Responsibility



- To participate as an ASC:
 - Must meet the definition of ASC (in 42 CFR § 416.2)
 - Have agreement with CMS
 - To qualify for an agreement: Must either
 - Have “deemed compliance” – accreditation by national accrediting body or licensed by State agency, or
 - Be surveyed by State survey agency

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ASC Definition



- Definition of ASC (42 CFR § 416.2):

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

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ASC Conditions for Coverage



- The 14 specific conditions for coverage all relate to the role of the Medical Director
- #1: Compliance w/State licensure req'ts (42 CFR § 416.40)
- #2: Governing body and management (42 CFR § 416.41)
 - Hospitalization: Effective procedure for immediate transfer to a hospital
 - ASC must periodically provide local hospital w/written notice of its operations and patient population served

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ASC Conditions for Coverage



- #3: Surgical services (42 CFR § 416.42): Likely direct area of Medical Director responsibility
 - This section contains detailed requirements relating to anesthesia, including:
 - Anesthetic risk & evaluation
 - Immediately before surgery
 - Before discharge from ASC
 - Who may administer anesthesia
 - Including supervision of nonphysician anesthetists – unless exemption for CRNAs under state law

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ASC Conditions for Coverage



- #4: Quality assessment & performance improvement (42 CFR § 416.43): Likely direct area of Medical Director responsibility
 - ASC must develop/maintain data-driven quality assessment & performance improvement program (“QAPI”)
 - Monitor effectiveness & safety of services
 - Monitor quality of care
 - Identify ways to improve care
 - Typically falls to Medical Director to oversee

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ASC Conditions for Coverage



- #5: Environment (42 CFR § 416.44): Likely shared responsibility between Medical Director & ASC
 - Physical environment – functional & sanitary environment for surgical services
 - Fire safety: Medical Director often must implement
 - Building safety: More for ASC to address (compliance with codes)
 - Emergency equipment: Must be immediately available for use & appropriate for ASC’s patient population
 - Typically an area for Med. Dir. to oversee & coordinate
 - Emergency personnel: Must have personnel trained in use of emergency equipment & CPR whenever a patient in the ASC

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ASC Conditions for Coverage



- #6: Medical Staff (42 CFR § 416.45): Likely shared responsibility between Medical Director & ASC
 - Membership & clinical privileges: Qualifications of members of the medical staff
 - Reappraisals: Must periodically reappraise privileges & scope of procedures performed in the ASC
 - Other practitioners: Must have policies & procedures to oversee & evaluate clinical activities of other practitioners
 - (On a practical basis, the Medical Director is usually the person called upon to deal with problems relating to Medical Staff members)

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ASC Conditions for Coverage



- #7: Nursing services (42 CFR § 416.46): Less a Medical Director responsibility
 - Must meet nursing needs of patients
 - Must delineate patient care responsibilities for all nursing personnel
 - Must be an RN available for emergency treatment whenever a patient is in the ASC

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ASC Conditions for Coverage



- #8: Medical records (42 CFR § 416.47): Likely shared responsibility between Medical Director & ASC
 - Must maintain complete & accurate medical records to ensure adequate patient care
 - ASC must have a system for collection, storage, & use of patient records
 - Form & content of record:
 - Must have medical record for each patient
 - Must be accurate, legible, and promptly completed
 - Typically will fall to the Medical Director to address failure of Medical Staff members to maintain proper records

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ASC Conditions for Coverage
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- Medical record must include at least the following:
 - Patient identification
 - Significant medical history & results of physical exam
 - Preop diagnostic studies (entered before surgery), if performed
 - Findings & techniques of the operation, including pathologist's report on all tissues removed during surgery
 - Any allergies & abnormal drug reactions
 - Entries related to anesthesia administration
 - Documentation of "properly executed informed patient consent"
 - Discharge diagnosis

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ASC Conditions for Coverage
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- #9: Pharmaceutical services (42 CFR § 416.48): Likely shared responsibility between Medical Director & ASC
 - Drugs must be prepared & administered acc'g to established policies & acceptable standards of practice
 - Adverse reactions must be reported to the responsible physician & documented in the record
 - Blood & blood products must be administered only by physicians or RNs
 - Orders given orally for drugs & biologicals must be followed by written order, signed by the prescribing physician

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ASC Conditions for Coverage
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- #10: Laboratory & radiologic services (42 CFR § 416.49): Likely shared responsibility between Medical Director & ASC
 - If ASC performs lab services, must meet CMS req'ts (42 C.F.R. Part 493)
 - Radiologic services may only be provided when integral to ASC services
 - Must meet hospital conditions of participation for such services (42 C.F.R. § § 482.26(b), (c)(2), & (d)(2)), including
 - Proper safety precautions
 - Periodic inspection of equipment
 - Periodic check of radiation workers for radiation exposure
 - Personnel – who may use radiologic equipment & administer procedures
 - Records

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ASC Conditions for Coverage
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- #11: Patient rights (42 CFR § 416.50): Likely shared responsibility between Medical Director & ASC
 - Verbal & written notice of patient's rights (pre-surgery)
 - **Disclosure of physician financial interest or ownership in the ASC
 - **Advance directives – provide info on policies on advance directives & document in prominent part of record whether patient executed an advance directive
 - Submission/investigation of grievances
 - Exercise of rights: Be fully informed about a treatment or procedure & expected outcome before performed
 - Privacy & safety
 - Confidentiality of clinical records

** Emphasizing rights that may not immediately come to mind as a "patient right"

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ASC Conditions for Coverage
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- #12: Infection control (42 CFR § 416.51): Likely shared responsibility between Medical Director & ASC
 - Must maintain program to minimize infections & communicable diseases
 - Must maintain functional and sanitary environment
 - Must maintain ongoing program to prevent, control, & investigate infections & communicable diseases
 - Must be under direction of designated & qualified profession w/training in infection control
 - Be part of QAPI

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ASC Conditions for Coverage
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- #13: Patient admission, assessment, & discharge (42 CFR § 416.52): Likely shared responsibility between Medical Director & ASC
 - Ensure each patient has appropriate presurgical & postsurgical assessments completed & all elements of discharge req'ts completed
 - Patient assessment & admission: Identify those patients who require medical history & physical exam prior to surgery
 - Include timeframe for med history & physical exam
 - Specific factors to address, including:
 - Patient age, diagnosis, type & number of procedures to be perf'd on same surgery date
 - Planned anesthesia level

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ASC Conditions for Coverage



- #13: Patient admission, assessment, & discharge cont'd:
 - Post-surgical assessment: Patient's post-surgical condition must be assessed by physician, qualified practitioner, or RN w/(at minimum) post-op care experience
 - Post-surgical needs must be addressed & included in discharge notes
 - Discharge: Must:
 - Provide written discharge instructions & overnight supplies
 - When appropriate, make follow-up appt
 - Ensure all pts informed – in advance of procedure or prior to leaving ASC – of their prescriptions, post-op instructions, & physician contact info for follow-up care

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ASC Conditions for Coverage



- #13: Patient admission, assessment, & discharge cont'd:
 - Discharge: Also must:
 - Ensure each patient has a discharge order signed by physician who performed the surgery or procedure
 - Ensure all patients discharged in company of a responsible adult
 - Except those patients exempted by attending physician

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ASC Conditions for Coverage



- #14: Emergency preparedness (42 CFR § 416.53): Likely shared responsibility between Medical Director & ASC
 - Must have emergency preparedness plan – reviewed & updated at least every two years – that:
 - Based on documented, facility-based & community-based risk assessment
 - Strategies to address emergency events
 - Address patient population & continuity of operations
 - Include process to cooperate w/local, state, & fed officials
 - Detailed req'ts of plan

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ASC Conditions for Coverage



- #14: Emergency preparedness (42 CFR § 416.53) cont'd:
 - System to track location of on-duty staff & sheltered patients during emergency
 - Safe evacuation from ASC, including detailed requirements – e.g.,
 - Care & treatment needs of evacuees
 - Staff responsibilities
 - Means to shelter in place
 - Medical documentation to
 - Preserve patient info
 - Protect confidentiality
 - Secure & maintain availability of records
 - Many more details

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ASC Conditions for Coverage



- The State Operations Manual contains the Interpretive Guidelines relating to the Conditions of Coverage (“CfCs”) for ASCs
- Far more detail
 - Details of the CfCs
 - Instructions for surveyors on what to review to assess compliance
- Topics often covered in more than one section – e.g.,
 - Informed consent is addressed in at least four sections:
 - Survey procedures
 - Surgical procedures
 - Medical records
 - Patient rights

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Highlights & Examples: Anesthetic Risk & Evaluation



- In discussing ASA physical status classification, CMS states (Q-0061):

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

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Highlights & Examples: Anesthetic Risk & Evaluation

- Post-anesthesia assessment
 - Before discharge from ASC
 - Not required for moderate or conscious sedation
 - By physician or anesthesiologist
 - Not by RN using a checklist
 - At a minimum, must include monitoring/assessment of:

• Respiratory function	• Temperature
• Cardiovascular function	• Pain
• Mental status	• Nausea & vomiting
	• Postop hydration

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Highlights & Examples: QAPI

- CMS does not prescribe a particular QAPI program; it provides each ASC with the flexibility to develop its own program
 - Ongoing: Collection & analysis of quality data at regular intervals, updated records of actions taken to identify quality problems identified
 - Data-driven: Must identify what data will be collected, how data will be collected & analyzed, frequency of collection
 - Focus on high-risk, high-volume, & problem-prone areas
 - Will differ from ASC to ASC

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Highlights & Examples: Informed Consent

- “A well-designed informed consent process” to include (Q-0162):
 - Description of proposed surgery, including anesthesia to be used
 - Material risks & benefits related to the surgery & anesthesia
 - “Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity”
 - Treatment alternatives
 - Who will conduct surgical intervention & administer anesthesia
 - Whether other physicians will participate
 - Whether qualified nonphysician practitioners will perform important parts of surgery or administer anesthesia

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Highlights & Examples: Informed Consent (2)

- Section on patient rights addresses informed consent for anesthesia (Q-0229)

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure.

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Potential Areas of Legal Exposure

Medical Director Areas of Responsibility

- Typically, the Medical Director is responsible for all of the above
 - Establishing policies and procedures (or working with others to establish them)
 - Implementing policies
 - Overseeing that training is done
 - Spot-checking for compliance
 - Preparing for and responding to surveys
- Serves as the “point person”: the “firefighter” who addresses the crisis du jour

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Potential Legal Exposure



- The role is prone to potential liability
- The Medical Director is in the hot seat
 - Fields all crises
 - Often – quick decisions needed
 - High stakes
- Many responsibilities that require ongoing oversight/monitoring
 - Makes it easier for a ball to drop
 - To fail to carry out all responsibilities
 - Potential consequences for ASC accreditation/Medicare participation

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Potential Legal Exposure



- With a wide range of responsibilities, many areas of potential legal exposure:
 - Noncompliance with CMS Conditions for Coverage
 - Likely a breach of the Medical Director agreement
 - Consequences for ASC accreditation/Medicare participation
 - Breach of contract – failure to comply with all duties of the position
 - Claims relating to credentialing
 - Failure to credential a physician
 - Termination of a physician's privileges
 - Negligent credentialing

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Potential Legal Exposure



- Additional areas of exposure:
 - Professional liability – if a patient is injured – whether due to
 - A failure to comply with Conditions for Coverage
 - A decision the Medical Director makes
 - Even if the decision is proper, potential for a legal challenge
 - Claims related to peer review
 - HIPAA
 - Fraud & abuse
 - Compliance with Stark – financial arrangements with physicians
 - Anti-kickback compliance

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Strategies to Navigate Obligations & Minimize/Mitigate Legal Exposure



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Strategies: Framing Duties: #1



- *Contractual*: Make sure Medical Director duties are:
 - Clearly outlined
 - Not overly broad
 - Take into account the ASC's role in assuring compliance with ASC regulatory requirements
 - Duties must be realistic
 - ASC must provide staff to assist the Medical Director to carry out duties
 - (See below for the need to create a team)

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Strategies: Framing Duties: #2



- *Contractual*: Frame obligations as “assisting in” and “overseeing” rather than performing all of the tasks and ensuring an outcome
 - For example:
 - Original: “Ensure compliance with CMS Conditions for Coverage”
 - Reworded: “Work with ASC staff with the goal of promoting compliance with CMS Conditions for Coverage”
 - Cannot overcommit in “ensuring” or “guaranteeing” an outcome

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Strategies: Training



- *Contractual:* The ASC should provide appropriate training for the Medical Director to equip the Medical Director to carry out the duties of the position
 - Can perform better with the proper tools
 - Learn from others who face similar challenges
 - Such time should “count” for purposes of the time commitment of the Medical Director

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Strategies: Adequate Time



- *Contractual and operational:* Ensure that any Medical Director agreement allows the Medical Director sufficient time to perform the duties
 - Often, the time allocation is tied to a budgeted amount of money, rather than a realistic assessment of the time needed
 - Cannot do the job properly if do not have sufficient time

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Strategies: Indemnification & Insurance



- *Contractual:* Want the ASC or ASC owner to indemnify the Medical Director against liability associated with the position, so long as the Medical Director acts in good faith
 - May also want to require that ASC/ASC owner purchase errors & omissions insurance to cover the Medical Director
 - Such agreement must survive expiration or termination of the Medical Director Agreement
 - This presentation is focused on the Medical Director, but such indemnification/insurance should extend to the anesthesia group & any group personnel who assist the Med. Dir. in carrying out duties

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Strategies: Create/Foster a Team



- *Operational:* Need to have a good team in the ASC to serve as extensions of the Medical Director and to oversee all of the ASC operations & obligations under the CMS participation agreement (as outlined above)
 - Not just the ASC Administrator, but all staff – from top to bottom
 - The Medical Director job is bigger than any one person

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Strategies: Create Redundancy in the Team



- *Operational:* Cross-train ASC and group (if the anesthesia group is providing the Medical Director) personnel on different functions
 - Promotes continuity of the function
 - Allows for informed discussion & decision-making
 - Provides more people to assist in
 - Implementing policies
 - Monitoring compliance
 - Providing training

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Strategies: Promote Culture of Compliance



- *Operational:* Create culture of compliance
 - Encourage staff to ask questions
 - Encourage ASC staff & Medical Staff members to
 - Offer suggestions
 - Think ahead to identify possible issues
 - Incorporate “training” into digestible units more frequently
 - To avoid overloading a single training session with more information than can be absorbed

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Conclusion

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Conclusion

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- The Medical Director is the point person in the ASC
 - An administrative position that is inextricably tied to clinical decision-making
 - High stakes/high-risk position
 - Similar to anesthesia – may be straightforward much of the time, but when a problem arises, the Medical Director must make a quick & informed decision
 - Understanding the scope of the obligations & the potential risks – along with strategies to minimize exposure – can help a Medical Director navigate the position

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