Are You READY for Your Next Survey?

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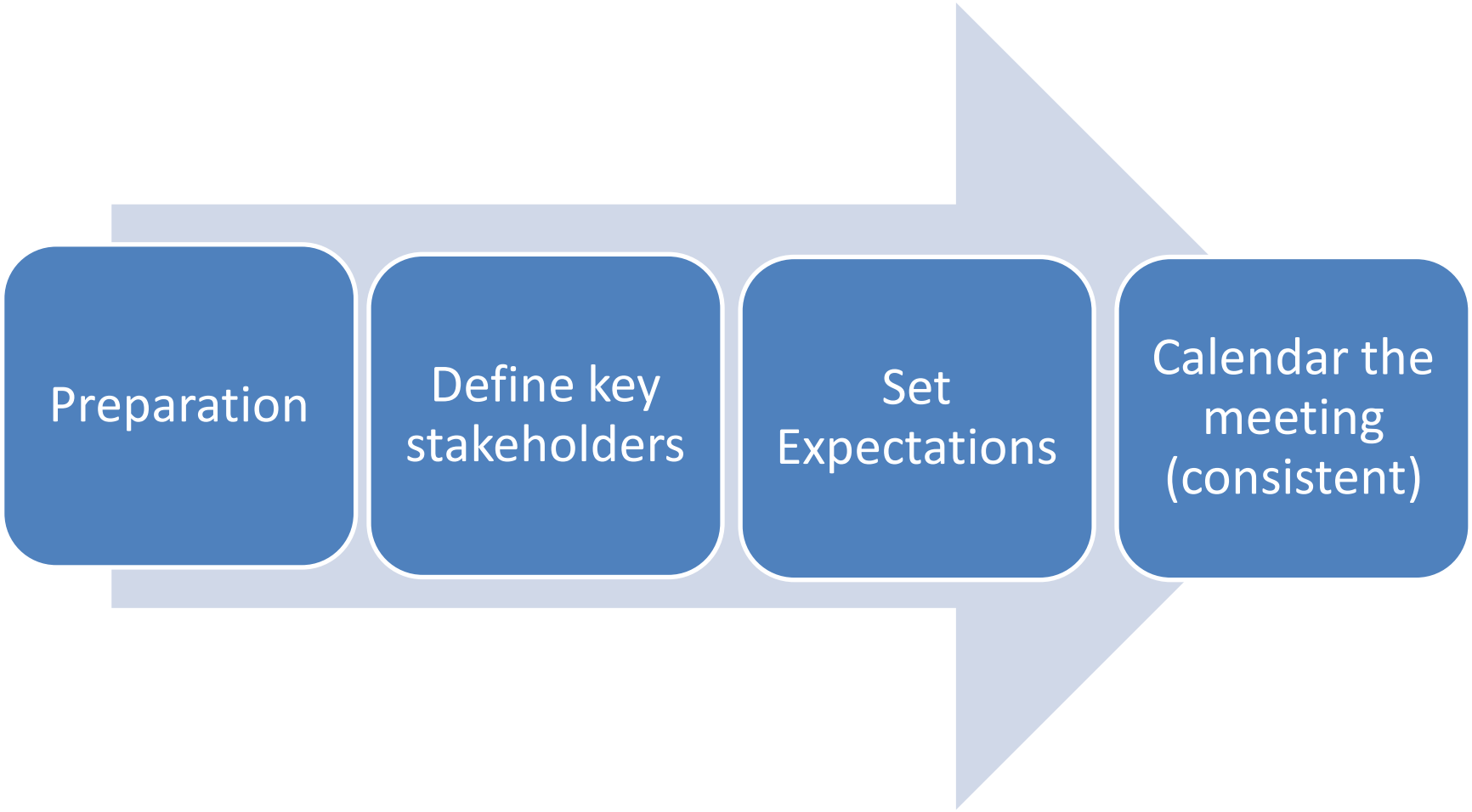
Senior Consultant

Amblitel

Learning Objectives Slide

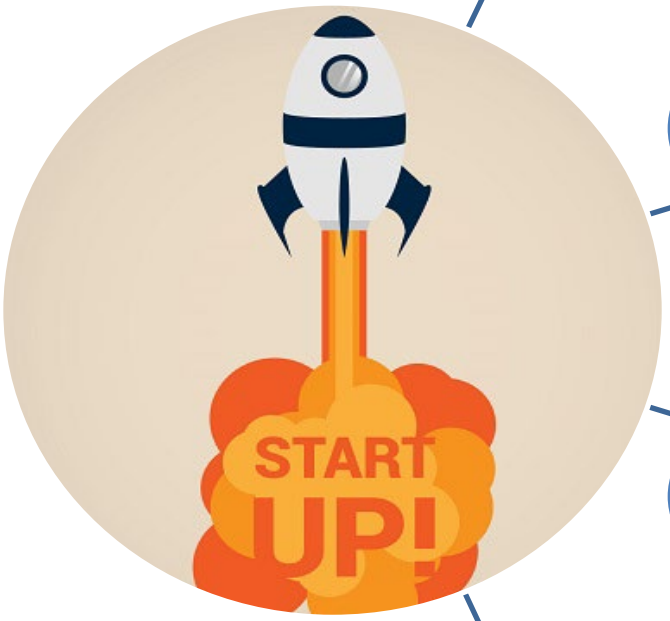
- Explain the difference between license, certification, and accreditation
- Provide guidance on prepping for a survey
- Identify 2 common deficiencies cited recently from accreditation organizations

Every Successful Survey starts with …..



Regulations and Standards Review

Prior Survey Deficiencies



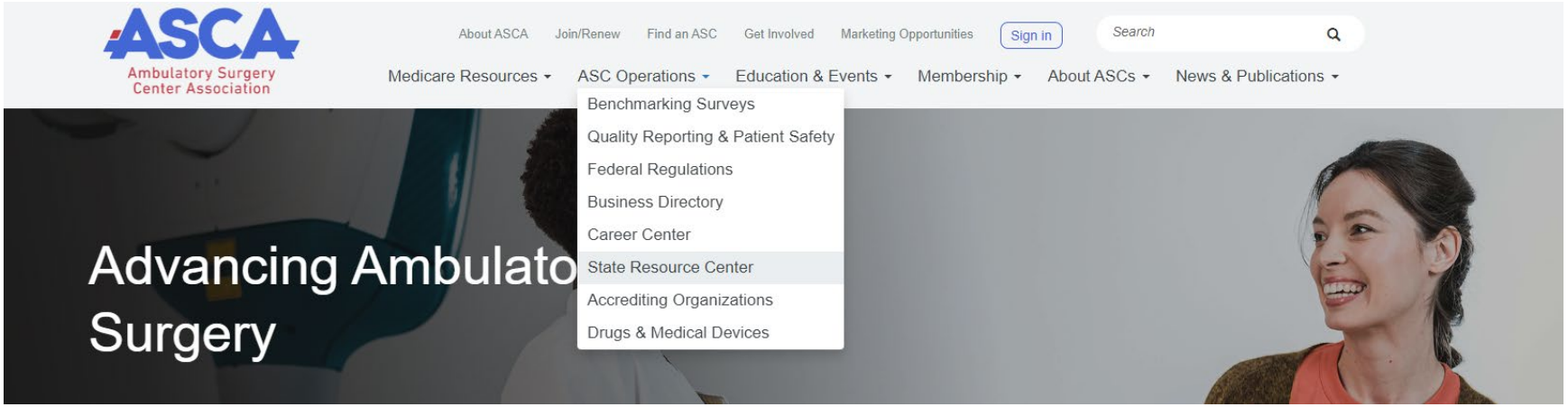
Mock Surveys and Audits

Critical Documents Binder (File)

State **Licensure**

- States may have a licensure requirement:
  - Pre-requisite to Medicare Certification
    - Must have this prior to applying for Medicare
  - Compliance through each State Department of Health
  - Authority having jurisdiction over the program.
  - Administrative Codes and State Statutes
  - Wide range of regulations, survey processes and timelines

ASCA Resource Page



State Resource Center

ASCA's State Affairs Department complements and supports the legislative and regulatory efforts of state ASC associations. In collaboration with state ASC associations and industry leaders, the State Affairs Department identifies and analyzes critical health policy issues concerning ASCs at the state level and promotes their ability to continue providing high-quality patient care.

State Law Database

ASCA's State Law Database is an interactive map that allows ASCA members to explore detailed information on statutory and regulatory requirements impacting ASCs across all 50 states.

State Affairs Committee

ASCA's State Affairs Committee was established to foster coordination between ASCA and the state associations and support state association operations.

State Associations

ASCA encourages its members to join their state associations and get involved in strengthening the ASC community at the state and local levels. Visit ASCA's State Associations page to find contact information for all active state associations.

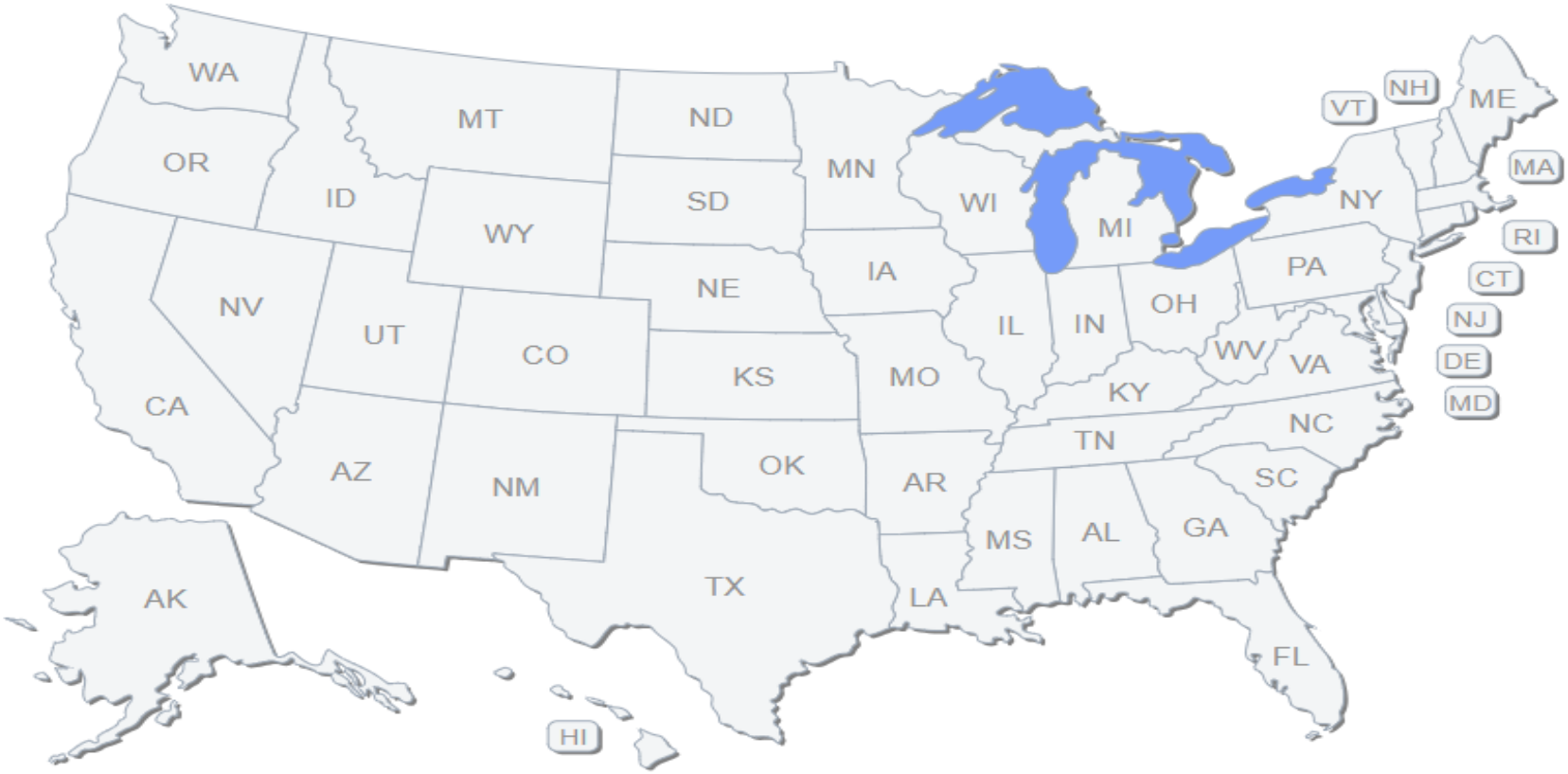
Government Affairs Update

ASCA publishes a weekly e-newsletter to ensure the ASC community stays informed.

State Laws & Regulations

Welcome to ASCA's interactive state law database, which allows members to explore detailed information on statutory and regulatory requirements that impact ASCs at the state level. This resource is updated on a regular basis to reflect any changes to state laws impacting ASCs.

Please select a state below to learn more.



Minnesota State Resources

Click on the heading tabs below to find out more information.

- License Requirements
- Ambulatory Surgery Center Definition
- Certificate of Need
- Medical History and Physical Examination
- Transfer Agreement
- Workers' Compensation
- Length of Stay Restriction

License Requirements

The state commissioner of health is hereby authorized to issue licenses to operate hospitals, sanitariums, outpatient surgical centers, or other institutions for the hospitalization or care of human beings, which are found to comply with the provisions of sections 144.50 to 144.56 and any reasonable rules promulgated by the commissioner. The commissioner shall not require an outpatient surgical center licensed as part of a hospital to obtain a separate outpatient surgical center license.

The licensing fee for an outpatient surgical center is $3,712. An additional fee of $1,800 will be charged to cover the cost of any initial certification surveys required to determined a provider's eligibility to participate in the Medicare or Medicaid program.

The commissioner may refuse to grant or renew, or may suspend or revoke, a license on any of the following grounds:

- Violation of any of the provisions of sections 144.50 to 144.56 or the rules or standards issued pursuant thereto
- Permitting, aiding, or abetting the commission of any illegal act in the institution
- Conduct or practices detrimental to the welfare of the patient
- Obtaining or attempting to obtain a license by fraud or misrepresentation
- If the commissioner determines that there is a pattern of conduct that one or more physicians who have a "financial or economic interest," as defined in section 144.6521, subdivision 3, in the hospital or outpatient surgical center, have not provided the notice and disclosure of the financial or economic interest required by section 144.6521

Advance Directives

Patient Safety Reporting Requirements

ASCs are required to document and report information on specified Adverse Events. Minnesota makes this information available to the public. More information on criteria and reporting requirements can be found here.

State Regulator

Minnesota Department of Health
Health Regulation Division
Golden Rule Building
85 East 7th Place
St. Paul, Minnesota 55101

Maria King, *Division Director, Health Regulation Division*
maria.king@state.mn.us
507.344.2716

Statutory & Regulatory References

Minnesota Revised Statutes: § 144.55 and § 144.56

Minnesota Administrative Rules:4675.0100

Centers for Medicare & Medicaid Services (CMS) **Certification**

ASC Conditions for Coverage (CfC)

42 CfC Part 416 of the Code of Federal Regulations

ASC's: Conditions for Coverage (CfC)

Hospitals: Conditions of Participation (CoP)

CMS: State Operations Manual (SOM)

Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers (Interpretive Guidelines)

State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

Table of Contents
(Rev. 215, 07-21-23)

State Operations Manual

Appendix I – Survey Procedures for Life Safety Code Surveys

(Rev. 209, 12-09-22)

Transmittals for Appendix I

Appendix Z

State Operations Manual
Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance

Table of Contents
(Rev.)

Transmittals for Appendix Z

§403.748, Condition of Participation for Religious Nonmedical Health Care Institutions (RNHCIs)

§416.54, Condition for Coverage for Ambulatory Surgical Centers (ASCs)

§418.113, Condition of Participation for Hospices

§441.184, Requirement for Psychiatric Residential Treatment Facilities (PRTFs)

§460.84, Requirement for Programs of All-Inclusive Care for the Elderly (PACE)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-41-ALL
REVISED 06.21.2021
REVISED 05.26.2022

DATE: **September 28, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance related to Emergency Preparedness- Exercise Exemption based on A Facility's Activation of their Emergency Plan

**** Revised to provide additional guidance and clarifications due to the ongoing COVID-19 public health emergency (PHE) ****

State Operations Manual

Appendix Q – Core Guidelines for Determining Immediate Jeopardy

Table of Contents
(Rev. 187, Issued: 03-06-19)

Transmittals for Appendix Q

Medicare Survey

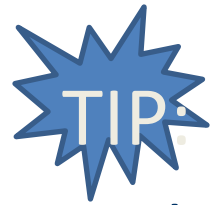
- Unannounced
- Performed by your State Agency(SA) or an approved accreditation organization
- Immediate access (within 15 mins.)
- Two-Part Survey
  - Health Operations
  - Life Safety
    - Can precede the survey of health requirement or done independently
    - LSC Surveyor need not be present for entire survey but presents findings and supporting documents to the team and is available during the exit interview (in-person or conference)

Who Can Perform Medicare Surveys on Behalf od Medicare?

Medicare Survey in Conjunction with AO

- This is called….
  - Medicare compliance AND the AO standards compliance
- Surveyors present their identification
  - TIP: Practice scenarios with registration team
- Ask for ASC leadership
  - Will not delay survey if Administrator is not available
- Process to inform owners and Governing body

Conference/Office Space



- Predetermine space
  - Close to leadership
  - Limit access to “other documents”
  - Large enough to conduct interviews, records and file review
  - List of how to contact the Administrator or DON with questions.

Opening Conference

- Sets tone of visit
  - Informative, brief and concise
- Survey scope explained
- Intro team, and additional surveyors (Lead)
- Timely receipt of all requested documents (1-2 Hours)
- Preliminary day and time of exit conference
- Determine lunch plan (time, allergies etc.)

Documents Requested

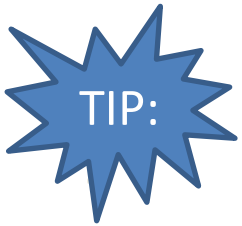
- List of employees, current Medical Staff, Allied Health professionals and other staff providing patient care
- Copy of Organizational chart
- Written Policies and Procedures
- Selected personnel records
- Various Programs:
  - Infection Prevention and Control
  - Quality
  - Emergency Preparedness
  - Risk Management etc.

Documents Requested

- Surgery schedule for days of visit
  - Patient progression from initial registration to discharge)
- All surgeries from the past 6 months
- All transfers from last visit

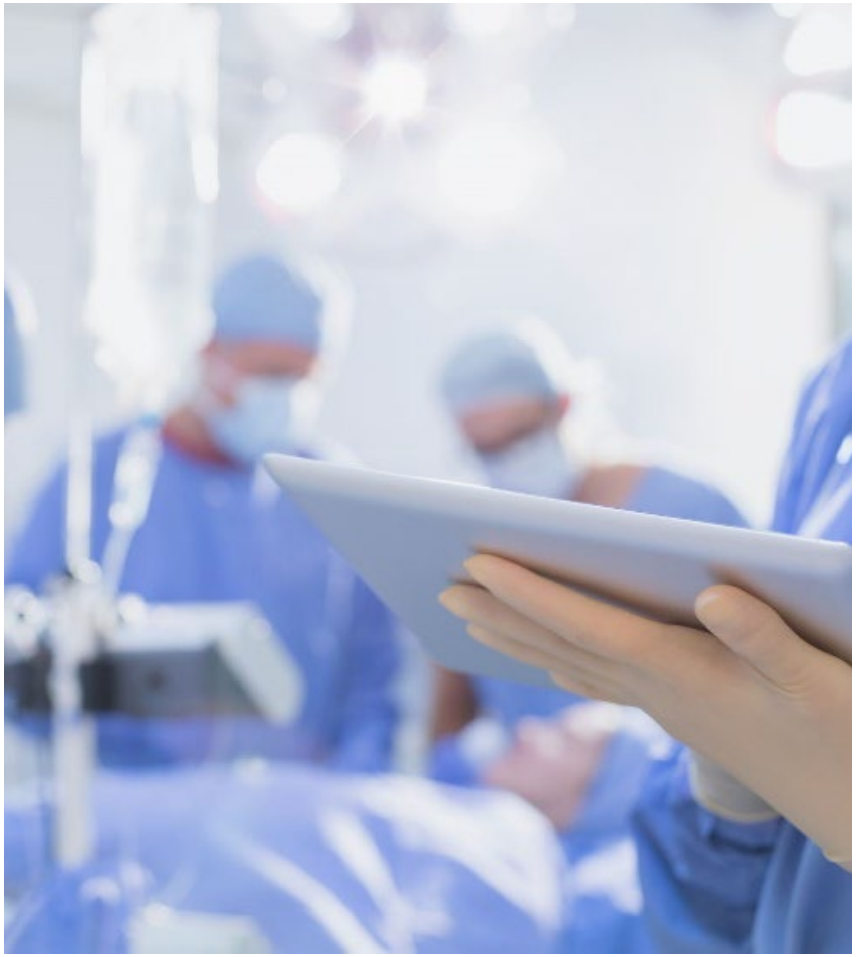
Documents Requested

- List of Contracted Services
  - Make sure you have current contracts
    - Consulting Pharmacist
    - Medical Director
    - Master Services etc.
  - Annual Board approval with Quality Reviews
- Copy of facility floor plan
- Maintenance records



Meeting minutes binder

Facility Tour / Patient Tracer



Tour:

- Layout, and general cleanliness (turn over activities)
- Staff and patient interactions (clinical and non-clinical)
- Protection of confidentiality
- Signage

Tracer:

- Handoffs
- Time Out
- IP processes:
  - Hand hygiene
  - Instrument flows (clean and dirty)
  - Medication administration
  - Food sanitation (expirations)
  - Regulated and non-regulated waste
  - Cleaning agents and SDS
  - MFU access

TIP: IP Nurse fills out form annually, shares document with team (Post!)

Exhibit 351

AMBULATORY SURGICAL CENTER (ASC) INFECTION CONTROL SURVEYOR WORKSHEET

(Rev. 206; 06-21-22)

Name of State Agency or AO (please specify)_____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

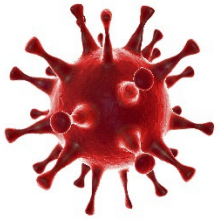
Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

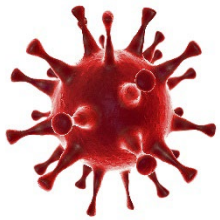
PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

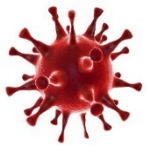
2. Address, State and Zip Code _____
Address

_____
City State Zip





Practices to be Assessed	Was Practice Performed?	Surveyor Notes
B. Syringes are used for only one patient (this includes manufactured prefilled syringes).	○ Yes ○ No ○ Unable to observe	
C. The rubber septum on a medication, whether unopened or previously accessed, vial is disinfected with alcohol prior to piercing.	○ Yes ○ No ○ Unable to observe	
D. Medication vials are always entered with a new needle.	○ Yes ○ No ○ Unable to observe	
E. Medication vials are always entered with a new syringe	○ Yes ○ No ○ Unable to observe	
F. Medications that are pre-drawn are labeled with the date and time of draw, initials of the person drawing, medication name, strength and beyond-use date and time	○ Yes ○ No ○ Unable to observe	
NOTE: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	○ Yes ○ No ○ Unable to observe	
b. Bags of IV solutions are used for only one patient (and not as a source of flush solution for multiple patients).	○ Yes ○ No ○ Unable to observe	
c. Medication administration tubing and connectors are used for only one patient	○ Yes ○ No ○ Unable to observe	



Medical Records

- Minimum of 20 records (10 if small facility)
  - Combo of active/closed (deaths and transfers)

Have 20 preselected

  - Expert: direct them to all the applicable sections on the record (electronic or paper)

Credentialing Files

- Standard format (electronic or paper)
- Review all files and be sure you are current with all documents that have expirations

TIP Highlight expiration dates for ease

TIP Administrator and/or Medical Director initials forms like NPDB or Claims history

TIP Have a checklist

Personnel Files

- Consistent and uniform
- Signatures
- Training documented
  - initial and ongoing
- Licenses
  - primary site verified and not expired
- Checklist

Preselect files (include ADM, DON, BOM and IP in that selection)

IP RN

Quality Lead

SPD personnel

Medication RN

Life Safety person

Anyone else they may meet along the way!

TYPICAL TEAMMATE INTERVIEWS (IN ADDITION TO THE ADMINISTRATOR, DON AND MEDICAL DIRECTOR)

Interviews

- Informal
- Completed through out visit
- Determine if facility are aware and understand how to comply with regulatory requirements, policies and procedures.

Post weekly tips with regulations or questions that might be asked during survey to prep team

Life Safety Questions

- What do you do in case of a fire?
  - R.A.C.E.
- Where is your CO2 extinguisher?
- Who is tracking your fire drills?
- How is fire risk incorporated into your process?
- Where are your medical gas shut off valves located? Who can turn them off? Who can turn them back on?
  - Which nurses can turn them off?
  - After retesting, Maintenance can turn them back on
- Why is it important to not block exits or fire extinguishers?
  - For your safety, when smoke fills the space, you will need to follow the glow of the exit sign to evacuate. Anything in that path, could create a delay or barrier for escape.
- What is an SDS and where would you find a copy?
  - It is a Safety Data Sheet of facts on how to manage hazardous chemicals. They are located online.

- Have you had any patient falls? What measures were in place prior to the fall? After?
- What are you doing for fall prevention?
- How are critical results reported? How are they documented?
- Can you name some strategies to identify that a patient is unfit for surgery today?
- How do you protect patient privacy?
- How are you doing with hand hygiene?
- Does anyone monitor hand hygiene practices?
- What are your initiatives to ensure the patient is ready for discharge?
- What are some Performance Improvement projects that you are proud of?
- What if the patient has a history of MRSA?
- How do you identify patients at risk for infections?
- Where is your eye wash station?
- Who monitors the eyewash
- Do vendors drop off loaner instruments?
- Where do venders check in?

2023 AAHC Quality Roadmap

January 2022 through Feb 28, 2023, v41 citations

1. Chapter 8: Emergency preparedness
   - Drills not scenario based nor completed on quarterly basis and not consistently evaluated
2. Chapter 2: Credentialing, Privileging and Peer Review
   - Missing reappointment supporting documents
   - Contracted providers and Allied Health not credentialed or privileged
   - Expired documents
   - Privileges for procedures not performed at the facility
   - Privileges missing for procedures performed (sedation, use of lasers, use of radiology equipment, U/S)
   - No formal process for peer review
   - No privileges for supervision of anesthesia services

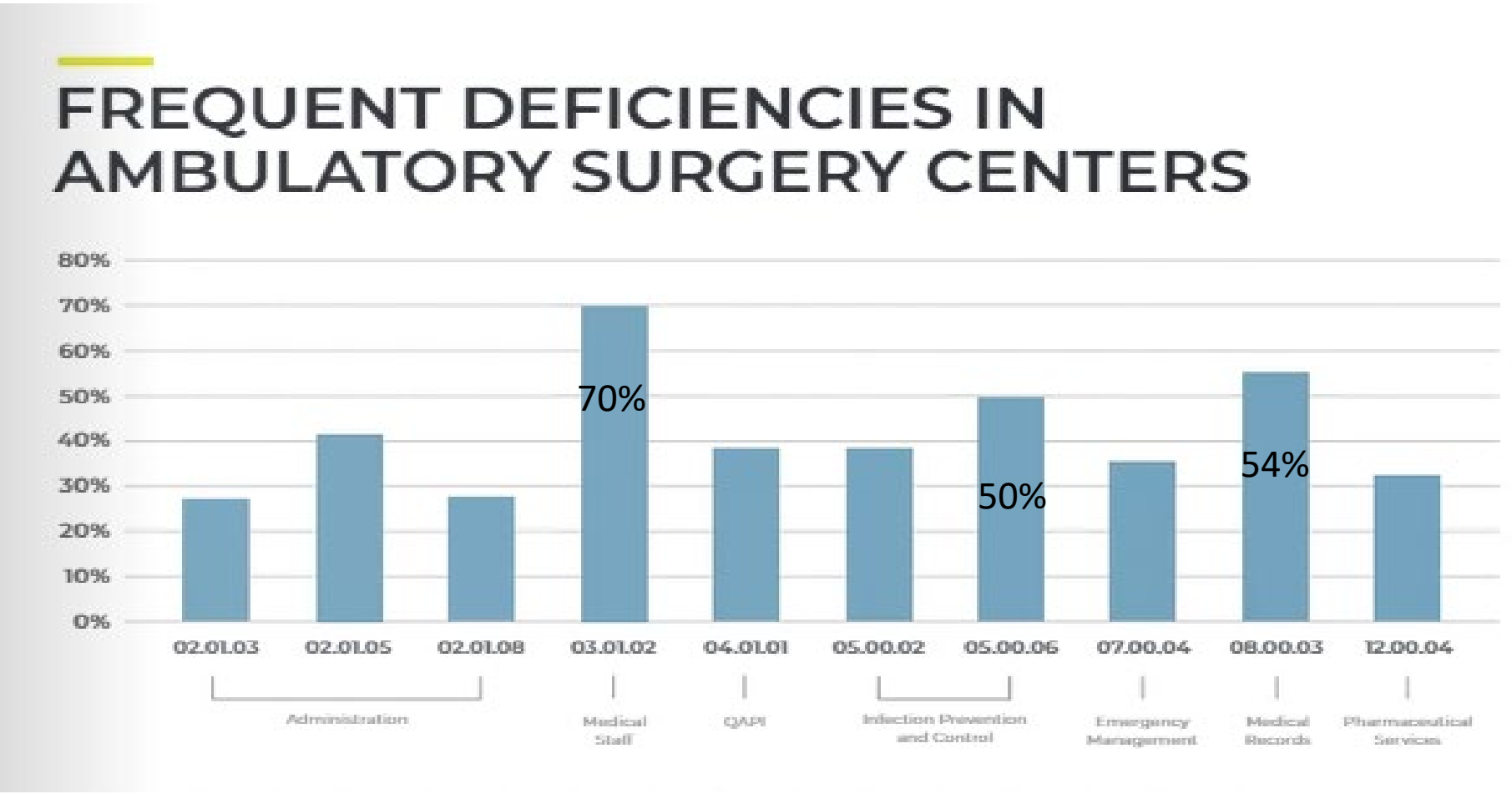
AAAAHC Quality Roadmap cont.

3. Documentation
   - Medication reconciliation not being performed or not consistently (inaccurate, lacking dosages, times etc.)
   - Allergies: missing sensitivities, reactions, not consistently updates, listed in several locations
4. Pharmaceutical services
   - Lacking list of high alert medications or ways to identify medications present
   - Confused drug names not labeled
   - No monitoring activities to high alert or meds with confused names
5. Quality
   - Studies not containing all components
   - No remeasurement
   - Unclear purpose, goals and date or corrective actions
   - No communication of studies
   - No external benchmarking

AAAAHC Quality Roadmap cont.

6. Infection Prevention
   - No formal Ip risk assessment
   - No surveillance for hand hygiene or safe injection practices
   - Hand hygiene not consistent with policy
   - Open vials not labeled
   - MIFU's not available
   - No policies for cleaning, disinfection or sterilization
   - Biological testing not completed per national guidelines
   - Hinged instruments not sterilized in open position
   - No list of high alert medications or process to identify
   - Confused drug names were not labeled

ACHC: June 1, 2022 through May 31, 2023



ACHC Deficiencies

1. Administration – Position Descriptions
   - Lack of: written position descriptions for IP Leader, Ethics and Compliance, Educator, and Safety Office
2. Administration - Personnel Records
   - Lacked evidence of: licensure verification, evidence of pre-affiliation competency validation, initial orientation annual appraisals, annual competencies or training, position description
3. Administration - Staff Training: Identification of Patient at Risk or Harm
   - Training on identification of patients at risk for harm to self or others no documented
4. Medical Staff – Credentialing Files
   - Files lacked: Two(2) references, written recommendations from other Healthcare professionals, Current (unexpired state licenses, DEA registration card, evidence of malpractice insurance, evidence of criminal background check, evidence of current board certification, NPDB and OIG queries, and evidence of current competence

ACHC Deficiencies continued…

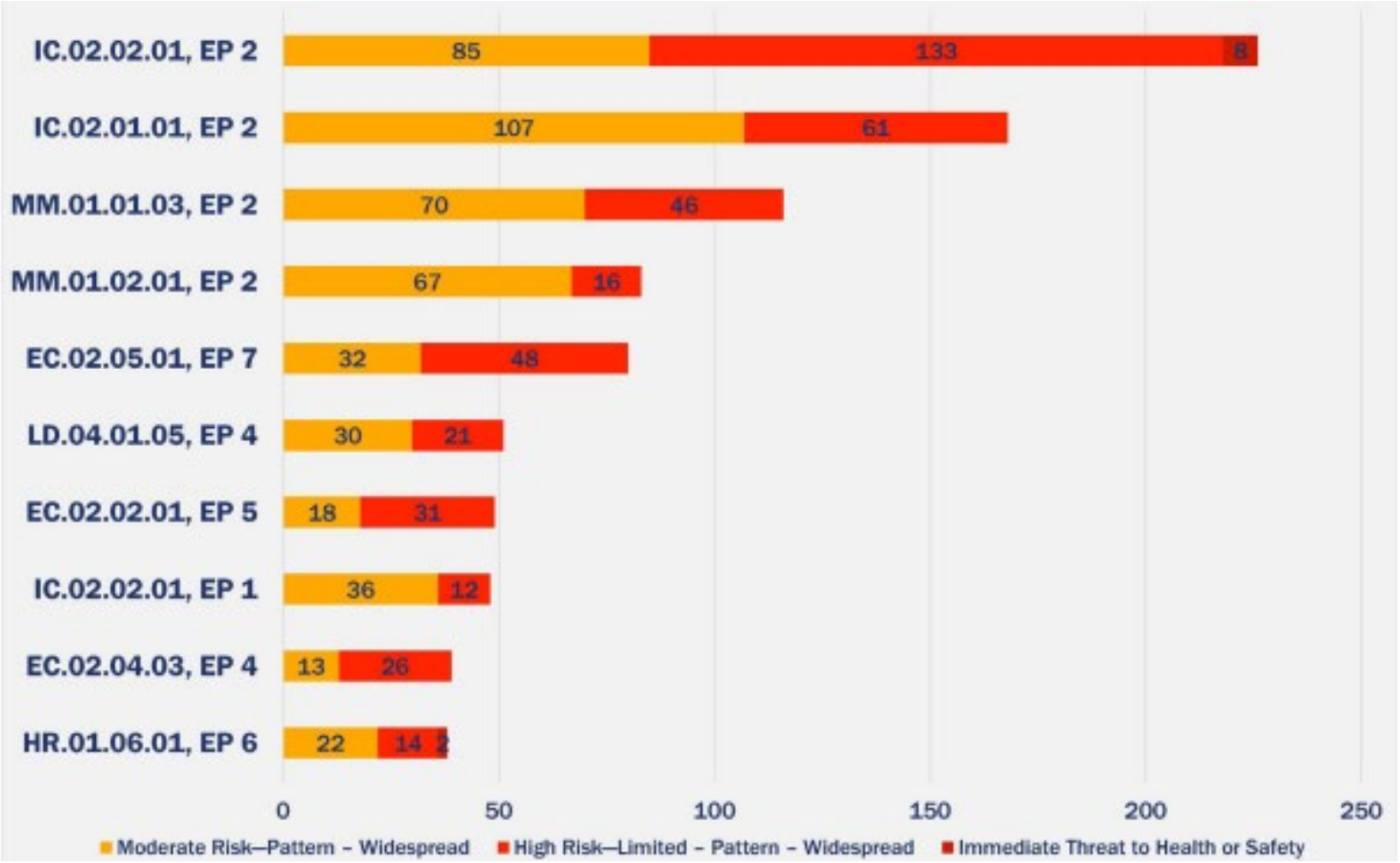
5. Quality Assessment/Performance Improvement – QAPI Plan
   - Plan was not written, plan did not include indicators to track and trend, did not include contracted services, staff interviewed did not have knowledge regarding quality activities and the annual QAPI plan lacked staff responsibilities, method of data collection and frequency of data collection
6. Infection Prevention and Control – Program Development
   - Staff not following hand hygiene policy, policy states organization follows CDC recommendations on hand hygiene but policy did not match, rust noted on casters, c-Arm cleaned in operating room prior to procedure end, Position descriptions identify required vaccinations and titers but no evidence of verification of either.
7. Infection Control and Prevention – Sanitary Environment
   - Gaps in seams of floors in OR's. Biohazardous waster containers uncovered in Biohaz room, Dirty linen from previous day remained in uncovered pre-op hamper, Residual tape adhesive noted on OR table cushions and glass cabinet, No evidence of pest/rodent control services, contracted services performed terminal cleaning on a weekly basis (not each day), corrugated boxes are stored with clean supplies.

ACHC Deficiencies continued…

8. Emergency Management – Patient Population
   - Plan did not address patient population or identify populations that would require additional assistance
9. Medical Records – Form and Content
   - Anesthesia informed consent did not contain name or group responsible for administering anesthesia, records lacked evidence that patients received notice of patient rights or advanced directives, lacked complete pre-op nursing assessment, dates and times missing on H&P, times were not noted for time out space, RN signatures missing on discharge instructions, full operative reports were missing
10. Pharmaceutical Services – Labeling and Storage of Medications
    - Dates and times missing from pre-operative antibiotics, pre-printed labels still lacked documentation, outdated hydrocodone elixirs, Insulin stored in nutrition refrigerator, pre-filled syringes of mitomycin C stored in freezer which does not follow MIFU, unlocked anesthesia carts when anesthesia was not present, outdated vials of ketamine, medication refrigerator located in a hallway was unlocked ad plugged into a regular outlet

The Joint Commission 2022 Most Frequent Cited Higher-Risk* Accreditation Requirements

(Jan through Dec 2022)



Standard	EP	Keywords/Topics
IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies. *See* Q3 2021 Heads-Up Report titled *Reducing Risk Associated with Reprocessing of Medical Equipment* on your organization's *Joint Commission Connect* extranet site.	**EP 2:** The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.*	• Intermediate and high-level disinfection and sterilization • Disinfection • Infection prevention • Instrument processing • Following manufacturers' instructions for use • Enzymatic cleaner
IC.02.01.01: The organization implements infection prevention and control activities. *See* Q1 2021 Heads-Up Report titled *Infection Prevention and Control Activities* on your organization's *Joint Commission Connect* extranet site.	**EP 2:** The organization uses standard precautions, including the use of personal protective equipment, to reduce the risk of infection.†	• Personal protective equipment • Standard precautions • Hand hygiene • Infection prevention and control plan • Reducing infection risk

* Standards and EPs listed reflect those findings cited in the moderate/pattern through high/widespread categories and Immediate Threat to Health or Safety.

† Some lists include more than 10 entries due to several standards having the same number of EP–level RFIs.

* *See also* EC.02.04.03, EP 4.

† *See also* EC.02.02.01, EP 3.

Standard	EP	Keywords/Topics
MM.01.01.03: The organization safely manages high-alert and hazardous medications *See* Q4 2019 Heads-Up Report titled *Safe Management and Use of Look-Alike/Sound-Alike and High-Alert Medications* on your organization's *Joint Commission Connect* extranet site.	**EP 2:** The organization follows a process for managing high-alert and hazardous medications.*	• Medication management • High-alert medications • Hazardous medication • Labeling • Medication safety
MM.01.02.01: The organization addresses the safe use of look-alike/sound-alike medication. *See* Q4 2019 Heads-Up Report titled *Safe Management and Use of Look-Alike/Sound-Alike and High-Alert Medications* on your organization's *Joint Commission Connect* extranet site.	**EP 2:** The organization takes action to avoid errors involving the interchange of medications on its list of look-alike/sound-alike medication.	• Look-alike/sound-alike medications • Medication errors • Medication safety
EC.02.05.01: The organization manages risks associated with its utility systems. *See* Q2 2020 Heads-Up Report titled *Management of Utility Systems* on your organization's *Joint Commission Connect* extranet site.	**EP 7:** In areas assigned to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation systems provide appropriate pressure relationships, air-exchange rates, filtration efficiencies, relative humidity, and temperature.	• Utility systems • Ventilation systems • Temperature • Humidity • Airborne contaminants • Gases • Fumes • Dust • Air-exchange rates • Pressure relationships

Standard	EP	Keywords/Topics
LD.04.01.05: The organization effectively manages its programs, services, or sites. *See* Q3 2022 Heads-Up Report titled *Leadership — Staff Accountability* on your organization's *Joint Commission Connect* extranet site.	**EP 4:** Staff are held accountable for their responsibilities.	• Management • Leadership • Oversight • Key operations
EC.02.02.01: The organization manages risks related to hazardous materials and waste.	**EP 5:** The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals.	• Hazardous materials • Hazardous waste • Selecting, storing, handling, transporting chemicals
IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies.	**EP 1:** The organization implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.	• Processes for cleaning equipment • Documentation logs • Soiled equipment • No evidence of cleaning • Glucometers • Manufacturers' instructions for use

Standard	EP	Keywords/Topics
EC.02.04.03: The organization inspects, tests, and maintains medical equipment.	**EP 4:** The organization conducts performance testing of and maintains all sterilizers. These activities are documented.†	• Inspecting • Testing • Maintenance of medical equipment • Sterilizers
HR.01.06.01: Staff are competent to perform their responsibilities. *See* Q3 2020 Heads-Up Report titled *Competency Assessments* on your organization's *Joint Commission Connect* extranet site.	**EP 6:** Staff competence is assessed and documented once every three years, or more frequently as required by organization policy or in accordance with law and regulation.	• Staff competencies • Documentation • Law and regulations

EP, element of performance; IC, Infection Prevention and Control; Q, quarter; MM, Medication Management; EC, Environment of Care; LD, Leadership; HR, Human Resources.

Accreditation without Medicare Deemed

- It’s a Choice!
- Putting onus of Medicare survey on your state
- Planned Survey (dates predetermined)
- Does not review the Medicare regulations
- Still requires intense preparation to meet all the standards
- Policies, logs, audits, processes, outcome of Care standards etc.

Lucky is NOT how I describe a successful survey!
It is meticulous preparation with the opportunity to showcase the great care you provide!

Mryan@amblitel.com

References

- Code of Federal Regulations, Part 416- Ambulatory Surgical Services https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416
- CMS Ambulatory Surgical Center Infection Control Surveyor Worksheet https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

References

- ASCA Resources https://www.ascassociation.org/govtadvocacy/stateresourcecenter/stateassociations
- Updated Guidance for Ambulatory Surgical Centers – Appendix L of the State Operations Manual (SOM) https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/updated-guidance-ambulatory-surgical-centers-appendix-l-state-operations-manual-som

References

- CMS SOM for ASCs Appendix I https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_i_lsc.pdf
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