



# MEDICARE RURAL HEALTH CLINIC (RHC) ACCREDITATION STANDARDS MANUAL

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AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES

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# **SURVEY INSTRUCTIONS**

Please complete the Standards Manual for the facility by assessing compliance with the standards contained in this book.

## **STANDARDS STRUCTURE**

Standards found in this book are organized by grouping relevant standards together.

These groupings are comprised of “Sections”, “Sub-sections”, and then individual

standard numbers. Each main “Section” is identified by a numerical value, “Sub-sections” have been assigned an alphabetical value, and the individual standards under the subsection have also been numbered. Based on this format, each standard has been assigned a unique identifier to include all three elements to indicate its location.

For example: The standard which states, “The rural health clinic is licensed pursuant to applicable State and local law” is the second standard under Section 14, Sub-section A. Therefore, the unique identifier for this standard is: 14-A-2.

Please note that not all standards are necessarily in continuous sequential order. Some numbers have been reserved for future use and do not appear in the manual. The groupings within the Sections and Sub-sections of this book are intended to separate standards into logical sets of standards. Based on 40 years’ experience, such groups are likely, but not guaranteed, to be found and assessed during the same portion of the survey process.

# STANDARDS BOOK LAYOUT

The standards manual layout consists of five columns. The function of each column are as follows:

**ID:**

This column contains the alphanumeric identifier for each standard.

**Standard:**

This column contains the text for each standard.

**CMS Ref:**

This column indicates the corresponding CMS regulatory reference, if applicable.

**Class:**

This column indicates the anesthesia classification, based on QUAD A definitions, that is applicable to the standard. Only facilities that provide anesthesia meeting the definition of one or more of the classifications listed in this column are required to comply with that particular standard.

**Score:**

This column is used to document compliance or non-compliance by the surveyor during the survey process; or, by the facility during self-assessment reviews for performance. As stated below, if 100% compliance is not achieved, the standard is marked as “deficient”.

## SCORING COMPLIANCE

The QUAD A accreditation program requires 100% compliance with each standard to become and remain accredited. There are no exceptions. If there is even one instance where a surveyor makes an observation of non-compliance, the standard is scored as “Deficient” and the facility will be required to submit a Plan of Correction, as well as evidence of completed corrections. There may be occasion where the surveyor observes non-compliance, but the facility is able to demonstrate that the deficiency has been corrected while the surveyor is still on-site. Applicable standard(s) will be given a score of deficient. To provide full context to QUAD A and CMS, the survey findings should illustrate that non-compliance was corrected in the presence of the survey team.

QUAD A does not confer accreditation until a facility has provided acceptable plans of correction and evidence of corrections for every deficiency cited. However, when a standard refers to "appropriate", "proper" or "adequate", reasonable flexibility and room for consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised.

## **NOTES:**

Click here to add notes.

## SECTION 1: BASIC MANDATES

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION B: BASIC MANDATES</b>				
<b>1-B-7</b>	Only recognized abbreviations are allowed to be used in the clinical record.		<p><b>Interpretive Guidance:</b> The intent for patient safety and documentation consistency is that the facility only uses an approved, recognized list of medical abbreviations for clinical record documentation. The facility must define and approve the abbreviations allowed to be used in the clinical record.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Validate the list of approved abbreviations and resources used, such as MedicineNet Medical Dictionary and Tabers Medical Dictionary, or facility-developed policy.</li> <li>• During clinical record review, note abbreviations used and ensure these are on the official abbreviation list adopted by the facility.</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>1-B-8</b>	<p>The facility must perform a self-survey review of compliance with all Quad A standards annually prior to the expiration date of its accreditation in each of the two years between Quad A onsite surveys. The self-survey documentation must be retained for a minimum of 3 years and include:</p> <ol style="list-style-type: none"> <li>1. A completed Self-Survey checklist</li> <li>2. A Plan of Correction for any standard identified as non-compliant</li> <li>3. Evidence that each plan of correction has been carried out to establish compliance with standards</li> <li>4. Evidence that findings from the self-survey have been reviewed, included in the facility's Quality Improvement Plan, and discussed in the facility's Quality Improvement meetings.</li> </ol>		<p><b>Interpretive Guidance:</b> The intent is to ensure that the facility performs annual self-surveys consistent with QUAD A requirements.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review the most recent self-survey for completeness. Are the required elements present?</li> <li>• Are the last 3 years of self-survey documentation available?</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION E: QUAD A- MANDATED REPORTING</b>				
<b>1-E-1</b>	Changes in facility ownership must be reported to the QUAD A Central Office within thirty (30) days of the change.		<p><b>Interpretive Guidance:</b> The intent of this standard is to ensure facility ownership is current and accurate in the facility's QUAD A file. There should be ownership change information only if the facility's ownership has changed.</p> <p><b>Evaluating Compliance:</b> Interview leadership about any changes to ownership and verify facility ownership with QUAD A records. If there is no evidence that an ownership change has occurred, this standard should be marked as compliant.</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>1-E-2</b>	Any change in the physician staff (physician, surgeon/proceduralist and anesthesiologist) must be reported in writing to the QUAD A office within thirty (30) days of the change. Credentials of new physician staff (medical license, evidence of board certification or eligibility, and delineation of privileges for the facility) must also be sent to the QUAD A Central Office within the same timeframe.		<p><b>Interpretive Guidance:</b> This standard aims to ensure that facility physician staff data is current and accurate in the facility's QUAD A file. Please note that only anesthesiologists who perform procedures (e.g., pain management procedures) are required to be reported under this standard. In addition, this standard does not include contract anesthesiologists.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Verify physician staff listing.</li> <li>• Review documentation of notifications to QUAD A. Are changes reported within 30 days?</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>1-E-3</b>	Any action affecting the current professional license of any licensed professional facility staff member must be reported in writing to the QUAD A office within ten (10) days of the time the facility becomes aware of such action.		<p><b>Interpretive Guidance:</b> The intent of this standard is to ensure that any adverse professional staff licensure actions are documented and that all clinically licensed staff have a current professional license in good standing. Adverse actions on clinical licenses can include suspension, expiration, probation, etc.</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>Note:</b> For RHCs, allied health professionals include certified nurse-midwives, clinical social workers, clinical psychologists, marriage and family therapists, and mental health counselors.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review with facility leadership the facility's process for identifying and reporting license status changes for the medical director, physicians, pain management staff, and other licensed facility staff.</li> <li>• Review clinical personnel files to determine if there is evidence of such action.</li> <li>• If licensure action has occurred, is there evidence that the action was reported timely to QUAD A?</li> </ul>	

## SECTION 2: FACILITY LAYOUT AND ENVIROMENT

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION B: FACILITY ENVIRONMENT</b>				
<b>2-B-1</b>	The facility must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.		<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>2-B-19</b>	Smoking is prohibited in the entire facility.		<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b> <ul style="list-style-type: none"> <li>Assess signage prohibiting smoking in the facility.</li> <li>Observe the practice of staff, patients, and families.</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>SUB-SECTION E: STORAGE</b>				
<b>2-E-3</b>	As applicable to the setting, outdated medical supplies, instruments, implants, and equipment are removed and destroyed in accordance with federal/national, state, provincial, and local regulations.		<b>Interpretive Guidance:</b> No outdated medical supplies, instruments, implants, or equipment are used in the provision of patient care. Outdated supplies, instruments, implants, or equipment may not maintain their sterility or integrity.  Medical supplies, instruments, implants, and equipment not stored within proper temperature settings may be considered expired for patient use. Some may require certain temperatures to maintain	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

			<p>potency.</p> <p>Sterile items that can be reprocessed a specific number of times (e.g., LMA and implant sizers) per the manufacturer's instructions for use must have documentation regarding the number of times the item has been processed.</p> <p>Re-processing "expired" supplies is not acceptable unless the item is implicitly approved for such, and the process is documented in the manufacturer's IFU. When the item does not come with cleaning and re-sterilization instructions, it must be considered a single-use item with a terminal expiration date.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Inspect and check for expired supplies, instruments, implants, and equipment used in the facility.</li> <li>• Check manufacturers' recommendations for accurate best use by date or expirations.</li> <li>• If expired supplies, instruments, implants, or equipment are observed, interview staff to determine if a procedure is in place to check expiration dates on a regular basis.</li> <li>• Are sterile items that can be reprocessed a specific number of times, reprocessed in accordance with the manufacturer's instructions for use? Is documentation present regarding the number of times the item has been reprocessed?</li> <li>• Interview staff.</li> </ul>	
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## SECTION 3: SAFETY

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION D: MEDICAL HAZARDOUS WASTE</b>				
<b>3-D-1</b>	All medical hazardous wastes (including desposable sharp items) are disposed of in sealed, labeled containers and stored in compliance with local, state/provincial, and national guidelines, and/or OSHA (Occupational Safety and Health Act) acceptable containers and separated from general refuse for special collection and handling.		<p><b>Interpretive Guidance:</b> The intent is to ensure safe practices when handling medical hazardous wastes.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review facility policies and procedures.</li> <li>Interview staff.</li> <li>Observe staff handling medical hazardous wastes.</li> </ul> <p><b>CDC Regulated Medical Waste, 2003</b>  <a href="https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste">https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste</a>.</p> <p><b>EPA Medical Waste, 2024</b>  <a href="https://www.epa.gov/rcra/medical-waste">https://www.epa.gov/rcra/medical-waste</a></p> <p><b>OSHA Hazardous Waste</b>  <a href="https://www.osha.gov/hazardous-waste/standards">https://www.osha.gov/hazardous-waste/standards</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>3-D-4</b>	Used disposable sharp items are placed in secure puncture-resistant containers that are located as close to the use area as is practical.		<p><b>Interpretive Guidance:</b> The intent is to employ safety practices to prevent needlestick injuries and the transmission of HIV, hepatitis A and B, and other bloodborne pathogens. Containers for disposing of used sharps should be based on the following National Institute for Occupational Safety and Health (NIOSH) criteria:</p> <ul style="list-style-type: none"> <li><b>Functionality:</b> Containers should be puncture-resistant, durable during installation and transport, and an appropriate size and shape. The closure</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

			<p>should be secure and minimize exposure during closure.</p> <ul style="list-style-type: none"> <li>• <b>Accessibility:</b> Containers should be upright and easy to operate while preventing the contents from spilling. The container should be placed in a visible location, within easy horizontal reach, and below eye level. The container should also be placed away from any obstructed areas, such as near doors, under sinks, near light switches, etc.</li> <li>• <b>Visibility:</b> Containers should be clearly visible to the healthcare worker. The container should be designed so that workers may be able to easily determine the container's fill status and distinguish any warning labels.</li> <li>• <b>Accommodation:</b> Containers should facilitate ease of storage and assembly, require minimal worker training, be easy to operate, and have a flexible design. They should also easily accommodate one-handed disposal of a sharps device. Product design should minimize sharp surfaces and cross-infection hazards. Installation and mounting systems should be safe, durable, stable, and cleanable.</li> </ul> <p>FDA-cleared sharps containers must be made of heavy-duty plastic, feature a tight-fitting, puncture-resistant lid, remain upright and stable during use, be leak-resistant, and be properly labeled with a hazardous waste warning. Additionally, sharps disposal containers should be disposed of when they are three-quarters full.</p> <p>Information regarding the mounting of sharps containers is based on general safety practices and recommendations from the FDA and OSHA guidelines. While there is no explicit regulation stating that sharps containers must be mounted, it is recommended to place them in stable and secure locations to prevent</p>	
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		<p>spills and ensure ease of access. Mounting is one way to achieve this stability and accessibility. If a large sharps container is on the floor, it must be secured to prevent accidental tipping. Sharp containers cannot be on wheels for the same reason.</p> <p>Sharps should not protrude out of the disposal container. Sharps containers should be changed out when they are three-quarters full to prevent overfilling, as recommended by the FDA. This helps avoid spills and reduces the risk of needlestick injuries.</p> <p>The Department of Transportation (DOT) has regulations concerning sharps disposal, particularly for containers transported off-site for disposal. These containers must be puncture-resistant and securely closeable to prevent leaks. For sharps containers to be eligible for reuse, they must meet stringent requirements: they must be FDA-approved as reusable medical devices, permanently marked to indicate their suitability as reusable containers, and disinfected effectively based on the type of infectious substance they previously contained.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review facility policy and procedures on the disposal of used sharps.</li> <li>• Are sharps disposal containers puncture-proof?</li> <li>• Are sharps disposal containers secured to prevent accidental tipping of the container?</li> <li>• Observe employees discarding used sharps.</li> <li>• Observe the placement of sharp containers. (i.e., Are they located close to the use of sharps? Are they placed at the appropriate height level (height of 52-56 inches?)</li> <li>• Are used sharps disposed of properly?</li> </ul> <p><u>CDC - Bloodborne Infectious Diseases - Stop Sticks :</u></p>	
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			<p><u>Sharps Disposal - NORA Workplace Safety and Health Topic</u></p> <p><b>FDA Sharps Disposal Containers</b>  <a href="https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers">https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers</a></p> <p><b>Department of Transportation (DOT) Regulations</b>  <a href="https://www.hercenter.org/regsandstandards/dot.php">https://www.hercenter.org/regsandstandards/dot.php</a></p> <p><b>NIOSH - <u>Selecting, Evaluating, and Using Sharps Disposal Containers</u></b>  <a href="https://stacks.cdc.gov/view/cdc/6386">https://stacks.cdc.gov/view/cdc/6386</a></p> <p><b>USDA - Safely Using Sharps</b>  <a href="https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers">https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers</a></p> <p><b>Sharps Contain Regulations: Your Guide, 2024</b>  <a href="https://www.danielshealth.com/knowledge-center/sharps-container-regulations-your-guide">https://www.danielshealth.com/knowledge-center/sharps-container-regulations-your-guide</a></p>	
<b>SUB-SECTION F: EXITS</b>				
<b>3-F-1</b>	Exit signs are posted and illuminated consistent with state/provincial, local, national regulations and/or NFPA and OSHA codes.		<p><b>Interpretive Guidance:</b>  The intent is that the facility has properly illuminated exit signs so that staff, patients and visitors can easily, quickly, and safely identify an exit to the outside in the event of a facility emergency that requires evacuation.</p> <p>While signs are not required to be “self-illuminating,” the exit signs must be illuminated with backup power in case of a power outage. A battery back up is acceptable.</p> <p><b>Evaluating Compliance:</b></p>	<p><input type="checkbox"/> Compliant  <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>



			<ul style="list-style-type: none"> <li>During the facility tour, observe all exit signs to ensure they are properly illuminated.</li> <li>Request that staff demonstrate the back-up power to the exit signs to assess compliance.</li> <li>Confirm exit signs are connected to emergency power.</li> </ul>	
<b>3-F-3</b>	There are sufficient emergency lights for exit routes and patient care areas in case of power failure.		<p><b>Interpretive Guidance:</b> The intent is that the facility has emergency lighting for exits and patient care areas in case of a power failure.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review facility policy and procedure on Power Failure.</li> <li>During the facility tour, observe emergency power sources for lights.</li> <li>Interview staff on what power source is available in patient care areas during a power failure and how the exits are illuminated during a power failure.</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>5-A-1</b>	Emergency cart is immediately available with a defibrillator or automated external defibrillator (AED), necessary drugs, and other CPR equipment (e.g. suction, pediatric defib pads) necessary for the patient population being served.		<p><b>Interpretive Guidance:</b> The intent is to have all necessary equipment together in one place and immediately available to manage an emergency in the OR or PACU at all times a patient is in the facility.</p> <p>This also means that if a contract anesthesia provider brings any emergency medications or equipment into the facility and removes any of these items when leaving the facility, the contract anesthesia provider must remain in the facility until all patients have been discharged from the PACU.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Inspect the emergency cart to ensure that it is equipped with the required working equipment, medications, and other CPR equipment.</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

			<ul style="list-style-type: none"><li>• Interview staff regarding the emergency cart contents.</li></ul>	
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## SECTION 5: IN CASE OF EMERGENCY

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION D: EMERGENCY PREPAREDNESS PLAN</b>				
<b>5-D-1</b>	The Provider/Supplier must comply with all applicable Federal, State, and local emergency preparedness requirements. The Provider/Supplier must establish and maintain an emergency preparedness program that meets the requirements of this section.	491.12 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>5-D-2</b>	Emergency plan: The Provider/Supplier must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every two (2) years.	491.12(a) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>5-D-3</b>	The plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.	491.12(a)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-4	The plan must include strategies for addressing emergency events identified by the risk assessment.	491.12(a)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-5	The plan must address patient population, including, but not limited to, the type of services the Provider/Supplier has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.	491.12(a)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-7	The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.	491.12(a)(4) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-9	Policies and procedures: The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, and the communication plan in standard 5-D-21. The policies and procedures must be reviewed and updated at least every two (2) years.	491.12(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-11	At a minimum, the policies and procedures must address safe evacuation from the Provider/Supplier.	491.12(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-12	Safe evacuation from the Provider/Supplier must include consideration of the care and treatment needs of evacuees.	491.12(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-13	Safe evacuation from the Provider/Supplier must include staff responsibilities.	491.12(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-15	Safe evacuation from the Provider/Supplier must include identification of evacuation locations, such as appropriate placement of exit signs.	491.12(b)(2)(iv) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-17	At a minimum, the policies and procedures must address a means to shelter in place for patients, staff, and volunteers who remain in the Provider/Supplier.	491.12(b)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-18	At a minimum, the policies and procedures must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.	491.12(b)(4)(i) Standard  491.12(b)(4)(ii) Standard  491.12(b)(4)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-19	At a minimum, the policies and procedures must address the use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.	491.12(b)(5) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-21	Communication plan: The Provider/Supplier must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years.	491.12.c Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-22	The communication plan must include names and contact information for Staff, Entities providing services under arrangement, Patients' physicians, Volunteers, and Other Provider/Suppliers within the same Medicare type.	491.12(c)(1) Standard 491.12(c)(1)(i) Standard 491.12(c)(1)(ii) Standard 491.12(c)(1)(iii) Standard 491.12(c)(1)(iv) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-23	The communication plan must include contact information for Federal, state, tribal, regional, and local emergency preparedness staff and Other sources of assistance.	491.12(c)(2) Standard 491.12(c)(2)(i) Standard 491.12(c)(2)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-24	The communication plan must include primary and alternate means for communicating with Provider/Supplier's staff and Federal, State, tribal, regional, and local emergency management agencies.	491.12(c)(3) Standard 491.12(c)(3)(i) Standard 491.12(c)(3)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-27	The communication plan must include a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).	491.12(c)(6) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-28	The communication plan must include a means of providing information about the Provider/Supplier's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.	491.12(c)(7) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-29	Training and testing: The Provider/Supplier must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, policies and procedures in standard 5-D-9, and the communication plan in standard 5-D-21. The training and testing program must be reviewed and updated at least every two (2) years.	491.12(d) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-30	The training program must consist of initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.	491.12(d)(1)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-31	The training program must provide emergency preparedness training at least every two (2) years.	491.12.d.1.ii Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-32	The training program must maintain documentation of all emergency preparedness training.	491.12(d)(1)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-33	If the emergency preparedness policies and procedures are significantly updated, the Provider/Supplier must conduct training on the updated policies and procedures.	491.12(d)(1)(iv) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-34	If the emergency preparedness policies and procedures are significantly updated, the Provider/Supplier must conduct training on the updated policies and procedures.	491.12.d.1.v Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-35	The Provider/Supplier must conduct exercises to test the emergency plan at least annually.	491.12(d)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-D-36	<p>The Provider/Supplier must participate in a full-scale exercise that is community-based every two (2) years; or</p> <p>When a community based exercise is not accessible, conduct a facility-based functional exercise every two (2) years; or</p> <p>If the Provider/Supplier experiences an actual natural or man-made emergency that requires activation of the emergency plan, the Provider/Supplier is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.</p>	<p>491.12(d)(2)(1) Standard</p> <p>491.12(d)(2)(i)( A) Standard</p> <p>491.12(d)(2)(i)( B) Standard</p>	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-D-37	<p>The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise as required by standard 5-D-36 is conducted, that may include, but is not limited to the following:</p> <p>A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or</p> <p>B) A mock disaster drill; or</p> <p>C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.</p>	<p>491.12(d)(2)(ii) Standard</p> <p>491.12(d)(2)(ii)( A) Standard</p> <p>491.12(d)(2)(ii)( B) Standard</p> <p>491.12(d)(2)(ii)( C) Standard</p>	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix Z</a></p>	<p><input type="checkbox"/> Compliant</p> <p><input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
5-D-38	<p>The Provider/Supplier must analyze the Provider/Supplier's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the Provider/Supplier's emergency plan, as needed.</p>	<p>491.12(d)(2)(iii) Standard</p>	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix Z</a></p>	<p><input type="checkbox"/> Compliant</p> <p><input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION E: Emergency Preparedness Plan – Integrated Healthcare Systems</b>				
<b>5-E-1</b>	If a Provider/Supplier is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the Provider/Supplier may choose to participate in the healthcare system's coordinated emergency preparedness program.	491.12(e) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>5-E-2</b>	If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.	491.12(e)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>5-E-3</b>	If elected, the unified and integrated emergency preparedness program must be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.	491.12(e)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-E-4	If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.	491.12(e)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-E-5	If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 5-D-4, 5-D-5, and 5-D-7.	491.12(e)(4) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-E-7	If elected, the unified and integrated emergency plan must also be based on and include a documented community-based risk assessment, utilizing an all-hazards approach.	491.12(e)(4)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
5-E-8	If elected, the unified and integrated emergency plan must also be based on and include a documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.	491.12(e)(4)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
5-E-9	If elected, the unified and integrated emergency preparedness program must include integrated policies and procedures that meet the requirements set forth in 5-D-9, a coordinated communication plan, and training and testing programs that meet the requirements in standards 5-D-21 and 5-D-29, respectively.	491.12(e)(5) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix Z</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

## SECTION 6: MEDICATIONS SECTION 6: MEDICATIONS

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION A: MEDICATIONS</b>				
6-A-1	The facility must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice and under the direction of an individual designated responsible for pharmaceutical services.		<p><b>Interpretive Guidance:</b> Medication errors are the most reported type of medical error. They are preventable events that can result in serious patient harm (e.g., disability, death) and occur during any phase of the medication-use process (i.e., from procuring the medication to monitoring the patient after administration). Adherence to national standards of practice is critical.</p> <p><b>Evaluating Compliance:</b></p> <p><b><u>AORN Guidelines in Practice: Medication Safety</u></b>  <a href="https://aornjournal.onlinelibrary.wiley.com/doi/epdf/10.1002/aorn.14034">https://aornjournal.onlinelibrary.wiley.com/doi/epdf/10.1002/aorn.14034</a></p> <p><b><u>USP 797 Key Changes (ashp.org)</u></b></p> <p><b><u>ASA Statement on Security of Medications in the Operating Room, 2023</u></b>  <a href="https://www.asahq.org/standards-and-practice-parameters/statement-on-security-of-medications-in-the-operating-room">https://www.asahq.org/standards-and-practice-parameters/statement-on-security-of-medications-in-the-operating-room</a></p> <p><b><u>AANA Safe Injection Guidelines for Needle and Syringe Use, 2022</u></b>  <a href="https://issuu.com/aanapublishing/docs/8-safe_injection_guidelines_for_needle_and_syringe_use">https://issuu.com/aanapublishing/docs/8 - safe injection guidelines for needle and syringe</a>  <a href="https://issuu.com/aanapublishing/docs/8-safe_injection_guidelines_for_needle_and_syringe_use?fr=sNzEyZTU2NDAxMjU">n?fr=sNzEyZTU2NDAxMjU</a></p> <p><b><u>American Society of Ophthalmic Registered Nurses (ASORN) Use of Multi-dose Medications</u></b></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<a href="https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/">https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/</a>  <b>Using Multidose Eyedrops in a Health Care Setting, 2014</b> <a href="https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216">https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216</a>  <b>USP General Chapter Labeling: Expiration Date FAQs December 2023</b>  <a href="https://www.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_gcl_au*MTE5NjEzMzM3OS4xNzA3NDE4MTA0*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA1*_ga_DTG_Q04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA..">sp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_gcl_au*MTE5NjEzMzM3OS4xNzA3NDE4MTA0*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA1*_ga_DTG_Q04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA..</a>	
6-A-2	Drugs must be prepared and administered according to established policies and acceptable standards of practice.		<b>Interpretive Guidance:</b> Note: Per the USP, expiration dates must be formatted using the year (in a 4-digit format), the month, and, if applicable, the day, separated by hyphens or forward slashes in accordance with USP 700 Updates December 2023.  Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for drug storage, the facility is expected to follow the labelled conditions.  <b>Evaluating Compliance:</b>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>CDC Single-Dose or Multi-Dose</b>  <a href="https://www.cdc.gov/injection-safety/media/pdfs/Injection-Safety-For-Healthcare-P.pdf">https://www.cdc.gov/injection-safety/media/pdfs/Injection-Safety-For-Healthcare-P.pdf</a></p> <p><b>CDC Safe Injection Practices</b>  <a href="https://www.cdc.gov/injection-safety/hcp/clinical-guidance/index.html">https://www.cdc.gov/injection-safety/hcp/clinical-guidance/index.html</a></p> <p><b>American Society of Ophthalmic Registered Nurses (ASORN) Use of Multi-dose Medications</b>  <a href="https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/">https://asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/</a></p> <p><b>Using Multidose Eyedrops in a Health Care Setting, 2014</b>  <a href="https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216">https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216</a></p> <p><b>USP General Chapter Labeling: Expiration Date FAQs December 2023</b>  <a href="https://go.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA0*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA1*_ga*DTGQ04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA..">go.usp.org/USP_GC_7_FAQs?_gl=1*9t81ki*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA0*_ga*MTY4NDc2Mjk5OS4xNzA3NDE4MTA1*_ga*DTGQ04CR27*MTcwNzQxODEwNC4xLjAuMTcwNzQxODEwNC4wLjAuMA..</a></p>	

6-A-5	Outdated medications are removed and destroyed in accordance with federal/national, state, provincial, and local pharmacy regulations.		<p><b>Interpretive Guidance:</b>  Drug expiration dates reflect the time period during which the product is known to remain stable and maintain its integrity, which means it retains its strength, quality, and purity when it is stored according to its labeled storage conditions. Medications not stored within proper temperature settings may be considered expired for patient use. Some medications may require certain temperatures to maintain potency (i.e., muscle relaxants). The manufacturer's instructions for storage and use must be followed.</p> <p>For domestic programs: If medications are on backorder, the expiration may be extended based on the FDA extended use date: <a href="#">Search List of Extended Use Dates to Assist with Drug Shortages   FDA</a></p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Inspect and check for expired medications.</li> <li>• Check manufacturers' recommendations for accurate best use by date or expirations. If expired medications are observed, interview staff to determine if a procedure is in place to check expiration dates regularly.</li> <li>• Review related medication storage policies.</li> <li>• Interview staff.</li> </ul> <p><a href="#">Search List of Extended Use Dates to Assist with Drug Shortages   FDA</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
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ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION D: CONTROLLED SUBSTANCES</b>				
<b>6-D-3</b>	<p>All controlled substance transactions, including daily counts and wastes, require verification by two (2) licensed members of the team. (For facilities with only Schedule IV and V controlled substances, one (1) licensed and (1) authorized member of the operating room team may document verification of daily counts and wastes.)</p> <p>These verifications must be completed on any day that the facility is open and/or controlled substances are administered and in compliance with federal/national, provincial, state, and local regulations. The facility must develop a policy detailing how unlicensed authorized individuals are authorized, if applicable.</p>		<p><b>Interpretive Guidance:</b> The intent is to prevent diversion of controlled substances.</p> <p>RNs, LPNs, and physicians are licensed personnel. Authorized personnel include other members of the operative team designated by the facility per its policy. Two (2) licensed professionals are preferred; however, it is recognized that smaller facilities may not have two licensed professionals present in the facility,</p> <p>An inventory count is necessary when using a hard copy or an electronic controlled substance log, including a medication dispensing machine such as a pyxis</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review facility policy for the appointment of unlicensed authorized individuals.</li> <li>• Review the controlled substance transactions in the log, including daily counts and waste, to determine if all transactions have been verified by two (2) licensed personnel or in Class A facilities using only Schedule IV and V controlled substances (1) licensed and (1) authorized personnel.</li> <li>• For any noted discrepancies, interview staff and review related documentation to determine what action was taken to resolve the discrepancy.</li> <li>• If evidence of theft or diversion is identified, has the facility reported this to the Drug Enforcement Administration (DEA) and law</li> </ul>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>enforcement, and state regulatory boards as required?</p> <p><u>Federal Controlled Substances Act: Ordering and Recordkeeping</u></p> <p><u>Pharmacist's Manual An Informational Outline of the Controlled Substances Act</u> DEA published manual</p> <p><b>DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act</b>  <a href="http://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf">www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf</a></p> <p><b>DEA Registration Q&amp;A</b>  <a href="https://deadiversion.usdoj.gov/faq/registration-faq.html">https://deadiversion.usdoj.gov/faq/registration-faq.html</a></p> <p><b>Narcotic Drugs: Handling and Documentation, 2023</b>  <a href="http://www.rn.org/courses/coursematerial-10004.pdf">www.rn.org/courses/coursematerial-10004.pdf</a></p> <p><b>DEA Theft/Loss Reporting</b>  <a href="https://www.deadiversion.usdoj.gov/21cfr_reports/theft/theft-loss.html">https://www.deadiversion.usdoj.gov/21cfr_reports/theft/theft-loss.html</a></p>	

6-D-4	There must be a record of receipt and disposition of all controlled substances. Records must be maintained for a minimum of three (3) years.		<p><b>Interpretive Guidance:</b> The intent is to prevent diversion of controlled substances.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review facility records to determine if records of receipt and disposition of all controlled substances are complete.</li> <li>• Review related facility policies and procedures.</li> <li>• Review the facility's DEA form 222.</li> </ul> <p><u>Federal Controlled Substances Act: Ordering and Recordkeeping</u></p> <p><u>Pharmacist's Manual An Informational Outline of the Controlled Substances Act</u></p> <p><b>DEA, Practitioner's Manual, An Informational Outline of the Controlled Substance Act</b> <u><a href="http://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf">www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf</a></u></p> <p><b>DEA Registration Q&amp;A</b> <u><a href="https://deadiversion.usdoj.gov/faq/registration-faq.html">https://deadiversion.usdoj.gov/faq/registration-faq.html</a></u></p> <p><b>Narcotic Drugs: Handling and Documentation,2023</b> <u><a href="http://www.rn.org/courses/coursematerial-10004.pdf">www.rn.org/courses/coursematerial-10004.pdf</a></u></p>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
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ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION E: ACLS/PALS ALGORITHM</b>				
6-E-5	There must be a written protocol for cardiopulmonary resuscitation (CPR). This protocol must include the provision for annual drills, staff training upon hire and annually, drill documentation, and retention of documentation for at least three (3) years.		<p><b>Interpretive Guidance:</b> The intent is to ensure that staff are prepared and knowledgeable in required roles and activities when cardiopulmonary resuscitation is needed.</p> <p>This protocol should include the various roles, who must respond, how CPR will be implemented, and individuals who should be called if assistance is required to maintain patient safety. The protocol is reviewed and tested annually and updated as necessary.</p> <p>Applicable staff must be trained upon hire and annually on the CPR protocol./Code Blue drill</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Interview staff to assess knowledge of the CPR protocol and other medical emergency protocols.</li> <li>• Review the protocols for all required elements and evidence that the protocol is reviewed and revised annually.</li> </ul> <p><a href="#">Algorithms   American Heart Association CPR &amp; First Aid</a></p> <p><a href="#">The Impact of Mock Code Simulation on the Resuscitation Practice and Patient Outcome for Children With Cardiopulmonary Arrest - PubMed (nih.gov)</a></p> <p><a href="#">Mock Drill Checklist (Code Blue) (16737)   PDF (scribd.com)</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION F: EMERGENCY MEDICATIONS</b>				
6-F-7	There must be a written protocol for cardiopulmonary resuscitation (CPR). This protocol must include the provision for annual drills, staff training upon hire and annually, drill documentation, and retention of documentation for at least three (3) years.		<p><b>Interpretive Guidance:</b> The intent is to ensure that staff are prepared and knowledgeable in required roles and activities when cardiopulmonary resuscitation is needed.</p> <p>This protocol should include the various roles, who must respond, how CPR will be implemented and individuals who should be called if assistance is required to maintain patient safety.</p> <p>Applicable staff must be trained upon hire and annually on the CPR protocol/Code Blue Drill.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Interview staff to assess knowledge of the CPR protocol.</li> <li>• Review the protocol for all required elements and evidence that the protocol is reviewed and revised annually.</li> <li>• Review applicable personnel files to determine the appropriate training has been provided initially upon hire and annually thereafter, and any time updates occur.</li> </ul> <p><a href="#">Algorithms   American Heart Association CPR &amp; First Aid</a></p> <p><a href="#">The Impact of Mock Code Simulation on the Resuscitation Practice and Patient Outcome for Children With Cardiopulmonary Arrest - PubMed (nih.gov)</a></p> <p><a href="#">Mock Drill Checklist (Code Blue) (16737)   PDF (scribd.com)</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, Parts 1 - 6</b>  <a href="https://www.ahajournals.org/toc/circ/142/16_suppl_2">https://www.ahajournals.org/toc/circ/142/16_suppl_2</a></p>	
<b>6-F-9</b>	<p>The following medication must be available in the facility at all times:  Anti-hypertensives.</p>		<p><b>Interpretive Guidance:</b>  The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served.</p> <p><b>Evaluating Compliance:</b>  Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the population served.</p>	<p><input type="checkbox"/> Compliant  <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
<b>6-F-10</b>	<p>The following medication must be available in the facility at all times:  Seizure arresting medication (a benzodiazepine, e.g. Midazolam).</p>		<p><b>Interpretive Guidance:</b>  The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities of first-line seizure-arresting medications are sufficient based on the population served.</p> <p>First-line seizure-arresting medications are fast-acting medications that include lorazepam, diazepam, clonazepam, midazolam (IV or nasal spray), and phenobarbital.</p> <p>Phenytoin is <b>not</b> considered a first-line seizure-arresting medication; it is a second-line medication used for established status epilepticus (20 – 40 minutes).</p> <p>It is often not possible to take a medication by</p>	<p><input type="checkbox"/> Compliant  <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>mouth during a seizure, and the medications used for emergency management of seizures are available in forms that can be injected into a muscle (IM), administered intravenously (IV, in a vein), used as a nasal spray, or administered rectally.</p> <p><b>Evaluating Compliance:</b> Review emergency medications to determine if the type, concentration, and quantity of these medications are always available in sufficient quantities based on the patient population served.</p> <p><b>Rescue Medications for Seizures</b> <a href="https://www.verywellhealth.com/medications-used-for-seizure-emergencies-5100921">https://www.verywellhealth.com/medications-used-for-seizure-emergencies-5100921</a></p> <p><b>Seizure Rescue Therapies</b> <a href="https://www.epilepsy.com/treatment/seizure-rescue-therapies#What-are-">https://www.epilepsy.com/treatment/seizure-rescue-therapies#What-are-</a></p> <p><b>Medical management of status epilepticus: Emergency room to intensive care unit</b> <a href="https://www.seizure-journal.com/article/S1059-1311(19)30204-3/fulltext">https://www.seizure-journal.com/article/S1059-1311(19)30204-3/fulltext</a></p>	
6-F-13	<p>The following medication must be available in the facility at all times: A narcotic reversal agent (e.g., aloxone, nalmeferene).</p>		<p><b>Interpretive Guidance:</b> The intent is to ensure adequate emergency medications and supplies are always available in the facility. The quantities are sufficient based on the population served.</p> <p>Reversal agents are defined as any drug used to reverse the effects of anesthetics, narcotics, or potentially toxic agents.</p>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>Evaluating Compliance:</b> Review the emergency medications to determine if a narcotic reversal agent is always available in the facility. Are the quantities sufficient for the population served?</p> <p><b>National Library of Medicine, Reversal agents in anesthesia and critical care, 2015</b>  <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4645356/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4645356/</a></p> <p><b>Overdose Reversal Medications (NIDA)</b>  <a href="https://nida.nih.gov/research-topics/overdose-reversal-medications">https://nida.nih.gov/research-topics/overdose-reversal-medications</a></p>	

## SECTION 7: INFECTION CONTROL

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION A: INFECTION CONTROL</b>				
7-A-11	A sterile field is used during all operations and procedures, as applicable.		<p><b>Interpretive Guidance:</b> The intent is to minimize the risk of infection.</p> <p>Creating and maintaining a sterile field is foundational to aseptic technique and encompasses practice standards that are performed immediately prior to and during a procedure to reduce the risk of infection.</p> <p><b>Evaluating Compliance:</b> Observe a procedure to determine if a sterile field is established and maintained throughout the procedure. Interview staff to determine if a sterile field is used for all procedures.</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>SUB-SECTION B: HAND HYGIENE</b>				

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
7-B-1	<p>Hand hygiene is performed in accordance with current nationally recognized and/or WHO guidelines and standards of practice. Periodic hand hygiene auditing must be a part of the facility's quality activities.</p> <p>For surgical/procedural facilities: Scrub facilities are provided for the operating room staff. Scrub products (as appropriate), soap, and alcohol cleansers are provided for the operating room staff, consistent with current adopted guidelines and standards of practice for hand hygiene.</p>		<p><b>Interpretive Guidance:</b> The intent is to minimize the risk of infection.</p> <p>Surgical hand antisepsis is the primary line of defense to protect the patient from pathogens on the hands of perioperative team members.</p> <p>Healthcare institutions conduct hand hygiene audits to build confidence in adherence to hand hygiene protocols. These audits are critical tools for assessing compliance, identifying areas for improvement, and ultimately enhancing patient safety. They are also great projects that can be incorporated into your facility's Quality Assurance and Performance Improvement (QAPI) program and Program Evaluation.</p> <p>A hand hygiene audit involves the systematic and unannounced observation and recording of hand hygiene practices based on predefined criteria. These criteria often align with guidelines set forth by leading health organizations, such as the World Health Organization (WHO) or the Centers for Disease Control and Prevention (CDC). The primary goal of these audits is not to penalize facility staff but to provide constructive feedback and educational support to improve hand hygiene practices.</p> <p>The process of a hand hygiene audit typically involves several key steps. Initially, a team of trained observers is established. These individuals are responsible for monitoring hand hygiene practices within the facility setting. The observers discreetly record hand hygiene actions, noting whether healthcare workers perform hand hygiene at the appropriate times.</p>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>This may include before touching a patient, before clean/aseptic procedures, after body fluid exposure/risk, after touching a patient, and after touching the patient's surroundings.</p> <p>The data collected during the audit is then analyzed to determine compliance rates. This analysis provides valuable insights into the hand hygiene practices of facility staff and identifies patterns or trends that may require attention. For instance, the audit may reveal that compliance is lower during certain times of the day or before performing a task. Such findings are essential for effectively targeting interventions and training programs. Following the analysis, the results of the hand hygiene audit are shared with the facility staff. This feedback is crucial for fostering a culture of continuous improvement. During feedback sessions, facility staff have the opportunity to discuss barriers to hand hygiene compliance and brainstorm solutions. Moreover, these sessions can serve as educational opportunities, reinforcing the reasons behind hand hygiene protocols and demonstrating proper hand hygiene techniques.</p> <p>Hand hygiene audits are a vital component of infection prevention and control programs in QUAD A accredited facilities. They provide a structured means of assessing hand hygiene practices, identifying areas for improvement, and fostering a culture of safety. They are great QAPI projects whose outcomes can be captured in QAPI program evaluations and Program Evaluations. Through diligent efforts to conduct and act upon the findings of hand hygiene</p>	

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			<p>audits, your facility can significantly reduce the transmission of infectious diseases and protect the health and well-being of your patients and staff.</p> <p><b>AORN e Guidelines for Hand Hygiene</b>  <a href="https://aornjournal.onlinelibrary.wiley.com/doi/abs/10.1002/aorn.13964">https://aornjournal.onlinelibrary.wiley.com/doi/abs/10.1002/aorn.13964</a></p> <p><b>Clinical Safety: Hand Hygiene for Healthcare Workers</b>  <a href="https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html">https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html</a></p> <p><b>CONSENSUS RECOMMENDATIONS - WHO Guidelines on Hand Hygiene in Health Care - NCBI Bookshelf (nih.gov)</b>  <a href="https://www.ncbi.nlm.nih.gov/books/NBK144035/#:~:text=When%20performing%20surgical%20hand%20antisepsis,are%20not%20necessary%20(IB)">https://www.ncbi.nlm.nih.gov/books/NBK144035/#:~:text=When%20performing%20surgical%20hand%20antisepsis,are%20not%20necessary%20(IB)</a></p> <p><b>World Health Organization (WHO)</b>  <a href="https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene">https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene</a></p> <p><b>Outpatient Surgery, How to Perform a Proper Hand Scrub, 2009</b>  <a href="https://www.aorn.org/outpatient-surgery/article/2009-May-how-to-perform-a-proper-hand-scrub">https://www.aorn.org/outpatient-surgery/article/2009-May-how-to-perform-a-proper-hand-scrub</a></p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION C: INSTRUMENT PROCESSING</b>				
7-C-1	The facility has a written protocol for the reprocessing of all instruments and disinfection of all equipment used in patient care consistent with the manufacturer's instructions for use.		<p><b>Interpretive Guidance:</b> The intent is to minimize the risk of cross-contamination and infection.</p> <p>A written policy and procedure are necessary to ensure that the reprocessing of instruments and disinfection of all equipment used in patient care occurs consistently and is in accordance with the manufacturer's instructions for use.</p> <p>Instrument and equipment processing may be performed off-site by an outside vendor under contract. When this service is performed through a contracted provider, it must be part of the facility's written quality improvement program.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review the written policies and procedures for reprocessing all instruments and equipment used in patient care.</li> <li>Interview staff regarding their knowledge of these policies and procedures.</li> <li>Are all reusable medical equipment and point-of-care devices (e.g., blood glucose meters and other point-of-care devices, blood pressure cuffs, oximeter probes, surgical instruments, endoscopes) cleaned and reprocessed (disinfected or sterilized) prior to use on another patient or when soiled in accordance with manufacturer's instructions for use?</li> <li>As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>the SOM  <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is <b>not</b> a required form for all facility types.</p> <ul style="list-style-type: none"> <li>• Is there a separation between clean and soiled equipment maintained to prevent cross-contamination?</li> <li>• Are the manufacturer's instructions for reprocessing consulted and adhered to?</li> <li>• Are the manufacturer's instructions for reprocessing reusable medical equipment and disinfecting patient equipment readily available and used to establish clear operating procedures and training content for the facility? Are instructions posted at the site where equipment reprocessing is performed?</li> <li>• Do reprocessing personnel have training in the reprocessing steps and the correct use of PPE necessary for the task?</li> <li>• Do personnel responsible for disinfecting patient care equipment have training?</li> <li>• Are the training and competencies of the personnel responsible for reprocessing and/or disinfection of patient equipment documented initially upon assignment of their duties, whenever new equipment is introduced, and periodically (e.g., annually)?</li> <li>• If the reprocessing of instruments is performed through a contracted service,</li> </ul>	



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>has this service been added to the facility's written quality improvement program?</p> <ul style="list-style-type: none"> <li>• Interview staff and review the written contract.</li> <li>• How does the facility ensure that the outside vendor meets all applicable QUAD A standards? Is a process in place to validate compliance, staff competence, quality, etc? Are these processes outlined in a written contract between the facility and the outside vendor?</li> </ul> <p><b>ANSI/AAMI ST79: 2017 &amp; 2020 Amendments; Comprehensive guide to steam sterilization and sterility assurance in health care facilities</b>  <a href="https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188">https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188</a></p> <p><b>CDC Recommendations for Disinfection and Sterilization in Healthcare Facilities, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html</a></p> <p><b>CDC Disinfection and Sterilization Guideline, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html">https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html</a></p> <p><b>CDC Disinfection of Healthcare Equipment, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html</a></p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<b>AORN Guideline Implementation: Surgical Instrument Cleaning, 2015</b> <a href="https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2015.03.005">https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2015.03.005</a>  <b>AORN Back to Basics: Instrument Cleaning, 2017</b> <a href="https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2017.01.001">https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1016/j.aorn.2017.01.001</a>  <b>AORN Surgical Instrument Decontamination: A Multistep Process, 2019</b> <a href="https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.12784">https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.12784</a>	

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7-C-4	Single-use devices are not reprocessed unless they are approved by the FDA for reprocessing. Reprocessing of these devices is done by an FDA-approved reprocessor.		<p><b>Interpretive Guidance:</b> The intent is to decrease the risk of cross-contamination and infections.</p> <p>Safe reprocessing of single-use devices requires the following:</p> <ul style="list-style-type: none"> <li>• FDA approval for re-use of single-use devices</li> <li>• Re-processing occurs in accordance with the manufacturer's instructions</li> <li>• These devices are intended for a limited number of additional uses after initial use and only after adequate cleaning, disinfecting, and re-sterilization by validated techniques as specified by the manufacturer</li> <li>• The manufacturer will not guarantee the integrity of the product once the designated number of re-sterilizations has been achieved.</li> </ul> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review policy and procedures. Are they consistent with the manufacturer's IFUs?</li> <li>• Interview staff.</li> <li>• Review the facility's documentation of the processing of single-use devices. Does the facility document the reprocessing details of each single-use device to enable product identification, device traceability, and number of sterilizations the device has undergone to ensure that the manufacturer's instructions are not exceeded?</li> </ul> <p><b>FDA Reprocessing Single-Use Medical Devices: Information for Health Care</b></p>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>Facilities</b>  <a href="https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-single-use-medical-devices-information-health-care-facilities">https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-single-use-medical-devices-information-health-care-facilities</a></p> <p><b>CDC Reuse of Single-Use Devices, 2008</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/reuse-single-use-devices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/reuse-single-use-devices.html</a></p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION D: STERILIZATION</b>				
7-D-2	<p>The facility has at least one autoclave which uses high pressure steam and heat, or all sterile items are single-use disposable or the facility has contracted with an outside vendor to process instruments.</p> <p>If soiled instruments are processed immediately for sterilization, they are to be treated with an enzymatic cleaner per the manufacturer's instructions for use.</p>		<p><b>Interpretive Guidance:</b> The intent is to ensure the proper sterilization of all instruments and minimize infections.</p> <p>Instrument and equipment processing may be performed off-site by an outside vendor under contract. When this service is performed through a contracted provider, it must be part of the facility's written quality improvement program.</p> <p><b>Intraocular Surgical Instruments</b> must be cleaned and sterilized in strict accordance with the manufacturer's instructions for use and nationally accepted standards of practice. Toxic anterior segment syndrome (TASS) is an acute severe inflammatory reaction to a toxic contaminant introduced into the anterior chamber during intraocular surgery. Cleaning and decontamination, which include thorough rinsing and flushing, should precede disinfection or sterilization. It is recommended that ophthalmic instrumentation should be cleaned separately from nonophthalmic surgical instruments. Contaminated and soiled instruments should also be cleaned in an area separate from where packaging and sterilization take place.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (<a href="https://www.cms.gov/Regulations-and-">https://www.cms.gov/Regulations-and-</a></li> </ul>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><a href="#">Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is <b>not</b> a required form for all facility types.</p> <ul style="list-style-type: none"> <li>• The processing of instruments and equipment may be performed off-site by an outside vendor under contract. Interview staff and review the written contract.</li> <li>• How does the facility ensure that the outside vendor meets all applicable QUAD A standards? Is a process in place to validate compliance, staff competence, etc.? Are these processes outlined in a written contract between the facility and the outside vendor?</li> <li>• If the reprocessing of instruments is performed through a contracted service, has this service been added to the facility's written quality improvement program?</li> <li>• Observe practice, if possible.</li> </ul> <p><b>ANSI/AAMI ST79:2017 &amp; 2020 Amendments; Comprehensive guide to steam sterilization and sterility assurance in health care facilities</b>  <a href="https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188">https://www.standards-global.com/wp-content/uploads/pdfs/preview/1997188</a></p> <p><b>AAO Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments - 2018</b>  <a href="https://www.aao.org/education/clinical-statement/guidelines-cleaning-sterilization-intraocular">https://www.aao.org/education/clinical-statement/guidelines-cleaning-sterilization-intraocular</a></p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p><b>Toxic anterior segment syndrome (TASS): A review and update, 2023</b>  <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10841787/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10841787/</a></p>	
<b>7-D-5</b>	<p>The facility must monitor each autoclave load for the appropriate mechanical indicators (e.g., time, temperature, and pressure).</p> <p>Chemical indicators (external and internal) must be used according to the sterilizer manufacturer's instructions. The use of a type 1 and type 5 indicator is required.</p> <p>Minimally, a biological indicator (spore test) is used weekly for each sterilizer. A biological indicator is required for every load containing implantable items.</p> <p>Evidence of sterilization assurance monitoring is recorded for every load and any corrective action is documented.</p>		<p><b>Interpretive Guidance:</b>  The intent is to minimize infections.</p> <p>Sterilization must be performed in accordance with the manufacturer's instructions for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments). Sterilizer equipment is monitored and tracked for sterility and proper functioning. This is generally done in the sterilization log.</p> <p><b>Physical/Mechanical Indicators (Monitors)</b>  Physical/mechanical monitors (embedded in the sterilization equipment) register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence that the sterilization system has met the set parameters (or has not, and corrective action is needed).</p> <p><b>Chemical Indicators</b>  Chemical indicators (as recommended by the manufacturer) should be placed on the outside and inside of each sterilized package unless the internal indicator is readable through the packaging material. Chemical indicators are</p>	<p><input type="checkbox"/> Compliant  <input type="checkbox"/> Deficient  <input type="checkbox"/> Not Applicable</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>grouped into 6 types based on how they work. Type 1 and Type 5 indicators are the most currently used.</p> <p><b>External Chemical Indicators</b></p> <ul style="list-style-type: none"> <li>· Type 1 Process Indicators are tapes or labels that change colors to show that the package has been exposed to the sterilization process. They should be applied to the outside of every package unless an internal indicator is visible.</li> <li>· Type 2 are Indicators for Specific Tests to detect air leaks, ineffective air removal, and the presence of non-condensable gases. Also known as the Bowie-Dick test, it is intended for daily use in dynamic-air-removal (pre-vac) sterilizers. They should be run through a cycle in an empty chamber before the first load of the day to test the system.</li> </ul> <p><b>Internal Chemical Indicators</b></p> <ul style="list-style-type: none"> <li>· Type 3 are designed to react to a single parameter (e.g., sterilization time, temperature, or pressure).</li> <li>· Type 4 are designed to react to multiple parameters of the sterilization process.</li> <li>· Type 5* are Integrating Indicators, that react to all critical parameters over a specified range of sterilization cycles. These indicators include a spore strip, in which changing color signals the cycle's ability to eliminate microbes. For use inside individual packs, peel pouches, and rigid containers.</li> <li>· Type 6** are Emulating Indicators, that react to a specific sterilization cycle and will show a small deviation in any of the critical parameters (sterilization time, temperature, or pressure).</li> </ul>	



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>*Class 5 Chemical Integrators react to the three critical variables of a steam sterilization cycle (time, temperature, and the presence of steam) of which the performance is required to correlate to a biological indicator (BI). As a result, Class 5 integrator results are like those of a BI and can detect failures where the selected temperature isn't reached. This failure condition is likely to occur when there is incorrect packaging and loading, air/steam mixtures, and/or incorrect cycle for load contents.</p> <p>**Risk: Class 6 Chemical Indicators (CI) react to the three critical variables for a specified cycle type, and their performance may or may not correlate to a Biological Indicator. It is important to realize that if you run multiple exposure times and temperatures, you must use a distinct Class 6 CI to monitor each cycle time and temperature. Because Class 6 CIs are not required to correlate to a BI, a Class 6 indicator could reveal a pass where a BI would indicate a failure.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review the facility policies and procedures.</li> <li>• Review the sterilization documentation.</li> <li>• Interview staff.</li> <li>• Observe practice if possible.</li> <li>• As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>).</li> </ul>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>This worksheet may help identify the types of observations surveyors should make in all facility types. This form may also help; however, it is <b>not</b> a required form for all facility types.</p> <p><b>CDC Recommendations for Disinfection and Sterilization Guidelines in Healthcare Facilities, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html#tocBox">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html#tocBox</a></p> <p><b>CDC Sterilization Practices, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html</a></p> <p><b>Halyard Health Sterilization Pouches: What You Need to Know About the Essential Medical Sterilization Product, 2023</b>  <a href="https://www.halyardhealth.com/articles/sterilization/sterilization-pouches-what-you-need-to-know">https://www.halyardhealth.com/articles/sterilization/sterilization-pouches-what-you-need-to-know</a></p>	
7-D-6	Sterile instruments and supplies are packaged according to the manufacturer's instructions for use (IFU) and sealed effectively. Self-sealing peel pouches must be folded on the crease and may only be double-pouched when the process is validated by the manufacturer.		<p><b>Interpretive Guidance:</b>  The intent is to ensure the safe packaging of sterile instruments and supplies and minimize infections.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Is consistent with the manufacturer's IFUs?</li> <li>• Interview staff.</li> <li>• Observe peel pouches for the following: <ul style="list-style-type: none"> <li>➢ Overfilled with instruments</li> <li>➢ Instruments in the closed position</li> <li>➢ Sealed effectively to ensure that the instruments remain sterile</li> </ul> </li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<ul style="list-style-type: none"> <li>➤ Only double-pouched if validated for such, inner pouch is not folded</li> <li>• Minimally, is the following information on the label of sterile supplies? <ul style="list-style-type: none"> <li>➤ Sterilizer used</li> <li>➤ Cycle or load number</li> <li>➤ Date of sterilization</li> </ul> </li> </ul> <p>As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is <b>not</b> a required form for all facility types.</p> <p><b>CDC Sterilization Practices, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html</a></p> <p><b>Understanding the Parts and Functions of Surgical Instruments for Sterile Processing, 2024</b>  <a href="https://sterileprocessingtech.org/understanding-the-parts-and-functions-of-surgical-instruments-for-sterile-processing/">https://sterileprocessingtech.org/understanding-the-parts-and-functions-of-surgical-instruments-for-sterile-processing/</a></p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
7-D-7	Each sterilized pack is labeled with the date of sterilization and, when applicable, with the expiration date. When the facility has more than one (1) sterilizer, labels must also identify the sterilizer used.		<p><b>Interpretive Guidance:</b> The intent is to ensure the safe labeling of sterilized packs and minimize infections.</p> <p>Adequate information on the package's label assists the facility in monitoring supplies that have time-related expiration dates and to track and recall instruments associated with a sterilization failure.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Minimally, is the following information on the label of sterile supplies? <ul style="list-style-type: none"> <li>➤ Sterilizer used</li> <li>➤ Cycle or load number</li> <li>➤ Date of sterilization</li> <li>➤ Expiration date, if applicable</li> <li>➤ Initials of the processor</li> </ul> </li> </ul> <p>As a resource, see Part 2, Section III. Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>). This worksheet may be used to assist surveyors in identifying the types of observations they should make in all facility types. This form may be used to assist surveyors; however, it is <b>not</b> a required form for all facility types.</p> <p><b>CDC Sterilization Practices, 2023</b> <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
7-D-9	Comprehensive monitoring records that include quality control are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.		<p><b>Interpretive Guidance:</b> The intent is to ensure that the sterilizer is not contaminated and minimize infections.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review sterilization or other disinfection process logs. Logs may be hard copy or electronic.</li> <li>For each sterilization cycle, are the following elements documented? <ul style="list-style-type: none"> <li>Type of sterilizer and cycle used</li> <li>Load identification number</li> <li>Load contents</li> <li>Exposure parameters (e.g., time and temperature)</li> <li>Operator's name or initials</li> <li>Results of mechanical, chemical, and biological monitoring.</li> <li>Number of re-sterilizations if applicable</li> </ul> </li> </ul> <p><b>CDC Sterilization Practices, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html</a></p> <p><b>CDC Best Practices for Sterilization Monitoring in Dental Settings, 2024</b>  <a href="http://www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html">www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
7-D-10	There is a written policy and procedure for the management of a positive biological indicator.		<p><b>Interpretive Guidance:</b> The intent is to ensure that positive biological indicators are managed consistent with the manufacturer's IFUs and minimize infections.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review the policies and procedures for the management of a positive biological indicator.</li> <li>Interview staff.</li> <li>Can instruments used within the time frame of the positive test be tracked?</li> </ul> <p><b>CDC Sterilization Practices, 2023</b>  <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html</a></p> <p><b>CDC Best Practices for Sterilization Monitoring in Dental Settings, 2024</b>  <a href="http://www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html">www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
7-D-11	Immediate use steam sterilization (IUSS) is not done on a routine or frequent practice.		<p><b>Interpretive Guidance:</b> The intent is to minimize infections.</p> <p>IUSS, formerly known as “flash sterilization, is defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one (1) case to another.</p> <p>The use of IUSS should be minimized. Situations when IUSS may be appropriate include:</p> <ul style="list-style-type: none"> <li>• When a specific instrument is needed for an emergency procedure.</li> <li>• When a non-replaceable instrument has been contaminated and needs to be replaced in the sterile field immediately.</li> <li>• When an item has dropped on the floor and is needed to continue a surgical procedure.</li> </ul> <p><b>IUSS is NOT acceptable in the following situations:</b></p> <ul style="list-style-type: none"> <li>• When used to compensate for inadequate inventory of surgical instrument sets</li> <li>• When a loaner tray was not brought to the facility in time for routine reprocessing</li> <li>• For implant devices, except in a documented emergency situation when no other option is available.</li> <li>• For post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or other prion-associated diseases.</li> <li>• On devices or loads that have not been validated with the specific cycle used; or</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<ul style="list-style-type: none"> <li>On devices that are sold by the manufacturer already processed and packaged as sterile and intended for single use only</li> </ul> <p><b>Evaluating Compliance:</b> As a resource, see Part 2, Section III, Single Use Devices, Sterilization, and High-Level Disinfection, of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM (<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf</a>). This worksheet may be used to assist with identifying the types of observations surveyors should make in all facility types. This form may be used to assist surveyors; however, it is <b>not</b> a required form for all facility types.</p> <ul style="list-style-type: none"> <li>Review the immediate use steam sterilization log to determine if IUSS is performed frequently and/or if more instruments should have been purchased for use.</li> <li>Observe practice, if possible.</li> </ul> <p><b>ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities</b> <a href="https://array.aami.org/doi/book/10.2345/9781570208027">https://array.aami.org/doi/book/10.2345/9781570208027</a></p> <p><b>APIC Immediate-Use Steam Sterilization</b> <a href="https://www.apic.org/Resource/TinyMceFileManager/Position Statements/Immediate Use Steam Sterilization 022011.pdf">https://www.apic.org/Resource/TinyMceFileManager/Position Statements/Immediate Use Steam Sterilization 022011.pdf</a></p> <p><b>CDC Flash Sterilization</b></p>	



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/flash-sterilization.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/flash-sterilization.html</a>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION F: CLEANING</b>				
7-F-4	All blood and body fluid spills are cleaned using medical-grade germicides that are virucidal, bactericidal, tuberculocidal, and fungicidal. A spill kit is available and readily accessible.		<p><b>Interpretive Guidance:</b> The intent is to ensure safeguards are in place to protect workers against health hazards related to blood and body spills.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Interview staff and review the policy and procedure specifying the method to clean up blood and body spills.</li> <li>• What type of germicides are used? Are the germicides medical grade? Are they virucidal, bactericidal, tuberculocidal, and fungicidal? Are they EPA-registered? If a spill occurs, observe the clean-up process.</li> <li>• Is a spill kit available and clearly labeled?</li> <li>• Is the spill kit accessible and located where spills are most likely to occur?</li> <li>• Do staff know where the spill kit is located?</li> <li>• Does the spill kit contain sufficient absorbent materials?</li> <li>• Does the spill kit include the necessary PPE?</li> <li>• Does the spill kit contain tools to contain and clean up spilled blood and body fluids?</li> <li>• Does the spill kit include instructions for proper disposal of used absorbent materials and contaminated waste?</li> </ul> <p><b>OSHA Worker Protections Against Occupational Exposure to Infectious Diseases</b>  <a href="https://www.osha.gov/bloodborne-pathogens/worker-protections">https://www.osha.gov/bloodborne-pathogens/worker-protections</a></p> <p><b>The Complete Guide to OSHA Spill Kit</b></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<b>Regulations, 2024</b> <a href="https://www.homecoreinspections.com/resources/osha-spill-kit-regulations">https://www.homecoreinspections.com/resources/osha-spill-kit-regulations</a>	
7-F-6	Instrument handling and reprocessing areas are cleaned and maintained.		<b>Interpretive Guidance:</b> The intent is to ensure that instrument handling and reprocessing areas are cleaned and maintained to minimize infection.  <b>Evaluating Compliance:</b> <ul style="list-style-type: none"> <li>• Interview staff.</li> <li>• Inspect instrument handling and reprocessing areas for cleanliness.</li> <li>• Review cleaning logs. Is cleaning done as specified in the facility's policies and procedures?</li> </ul> <b>CDC Cleaning, 2023</b> <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/cleaning.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/cleaning.html</a>  <b>CDC Disinfection and Sterilization Guidelines</b> <a href="https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html">https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable  Enter observations of non-compliance, comments, or notes here.

## SECTION 8: CLINICAL RECORDS

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION A: GENERAL CLINICAL RECORDS</b>				
8-A-6	Electronic health records (EHR) must comply with security and privacy obligations under current HIPAA regulations.		<p><b>Interpretive Guidance:</b> The intent is to ensure that the facility takes measures to protect electronic health information to ensure confidentiality, integrity, and security in accordance with current HIPAA regulations.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Does the EHR comply with current HIPAA regulations?</li> <li>Is the EHR password protected?</li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
8-A-8	Clinical records for each patient must be accurate, legible, and promptly completed.		<p><b>Interpretive Guidance:</b> The intent is to ensure that clinical records are accurate, legible and completed promptly.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Interview staff and review policies, procedures, and clinical records.</li> <li>Do clinical records include at least the following? <ul style="list-style-type: none"> <li>(1) Patient identification;</li> <li>(2) Significant medical history and results of physical examination (as applicable);</li> <li>(3) Pre-operative diagnostic studies (entered before surgery), if performed (if applicable);</li> <li>(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body (if applicable);</li> </ul> </li> </ul>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>(5) Any allergies and abnormal drug reactions;</p> <p>(6) Entries related to anesthesia administration (if applicable);</p> <p>(7) Documentation of properly executed informed patient consent; and</p> <p>(8) Discharge diagnosis.</p> <ul style="list-style-type: none"> <li>Are all entries accurate, legible, authenticated, and promptly completed?</li> </ul>	
8-A-9	Clinical records must be retained the number of years as required by state and/or federal law; or a minimum of three (3) years to comply with the QUAD A three-year survey cycle.		<p><b>Interpretive Guidance:</b> The intent is to ensure clinical records are retained for a minimum of three (3) years.</p> <p>Clinical records may be in an electronic or paper-based format or a combination of both.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Interview staff.</li> <li>Are clinical records retained for the number of years required by QUAD A, and state law? The more stringent requirement applies.</li> <li>What is the process for destroying paper-based records? Who is authorized to destroy clinical records?</li> <li>Are paper-based records destroyed after conversion to an EMR within a reasonable timeframe? Once the data conversion is successfully completed, it is safe to destroy all paper-based information.</li> </ul>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
8-A-10	Clinical records are maintained and easily accessible by the accredited facility.		<b>Interpretive Guidance:</b> The intent is to ensure that clinical records are maintained and easily accessible.  Clinical records may be in an electronic or paper-based format.  <b>Evaluating Compliance:</b> Interview staff.	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>SUB-SECTION B: PRE-OPERATIVE DOCUMENTATION</b>				
8-B-1	Clinical records must contain patient identification.		<b>Interpretive Guidance:</b>   <b>Evaluating Compliance:</b>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

## SECTION 11: PERSONNEL

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>Sub-section C: Surgeons/ Proceduralists/ Etc.</b>				
<b>11-C-6</b>	The facility must have written policies and procedures that address the criteria for clinical staff privileges and the process that the facility's leadership body uses when reviewing physician, APRN, and PA credentials and determining whether to grant privileges and the scope of the privileges for each practitioner.		<p><b>Interpretive Guidance:</b>  Each practitioner who performs surgery or procedures in the facility, including those directly employed and those under contract, has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the facility. The facility's leadership is responsible for reviewing the qualifications of all practitioners recommended by qualified medical personnel and granting surgical privileges as the facility's leadership determines appropriate.</p> <p>The medical staff includes physicians, surgeons, specialists, CRNAs, NPs, PAs, and allied health professionals, as identified in facility policy.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Interview staff.</li> <li>• Review personnel files to verify that medical staff have been granted clinical privileges.</li> <li>• Review leadership and peer review meeting minutes.</li> </ul> <p><b>CMS expands medical staff definition to include APRNs, PAs</b>  <a href="https://www.fiercehealthcare.com/healthcare/cms-expands-medical-staff-definition-to-include-aprns-pas">https://www.fiercehealthcare.com/healthcare/cms-expands-medical-staff-definition-to-include-aprns-pas</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

## SUB-SECTION E: Facility Staffing

11-E-5	<p>All individuals using the clinic must meet one (1) of the following criteria:</p> <ol style="list-style-type: none"> <li>1. A Doctor of Medicine</li> <li>2. A Doctor of Osteopathy</li> <li>3. Physician Assistant</li> <li>4. Nurse Practitioner</li> <li>5. Nurse Midwife</li> <li>6. Psychologist</li> <li>7. State Licensed Mental Health Professional (Social worker, Marriage and Family Therapist, Professional Counselor)</li> </ol>		<p><b>Interpretive Guidance:</b> The intent is to ensure that all practitioners providing services are qualified and meet the criteria listed.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Interview staff.</li> <li>• Review personnel files for related documentation and evidence of primary source verification.</li> </ul>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
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## SUB-SECTION I: PERSONNEL TRAINING

11-I-1	<p>Each personnel record has evidence of annual hazard safety training.</p>		<p><b>Interpretive Guidance:</b> Hazard identification training ensures that every employee understands the hazards they are likely to encounter in the course of their job, and how to identify each one. Control training ensures that they know what to do when they encounter each hazard (biological, chemical, physical, safety, psychosocial).</p> <p>General online training is not acceptable. The hazard safety training is facility specific. Online training using a learning management system (LMS) is acceptable.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>• Review personnel files.</li> </ul>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
11-I-2	<p>Each personnel record has evidence of annual blood borne pathogen training.</p>		<p><b>Interpretive Guidance:</b> Exposure to blood borne pathogens is a risk to the employee's health. Bloodborne pathogen training</p>	<p><input type="checkbox"/> Compliant <input type="checkbox"/> Deficient</p>



			<p>ensures that every clinical staff member can identify risks of exposure, prevent exposure by taking proper precautions, and take effective action in the event of exposure.</p> <p>This standard does not apply to administrative staff.</p> <p>Training may be in person or online.</p> <p>Online training courses approved by the facility are acceptable if permitted by facility policy. Online courses are reviewed for appropriateness and approved by the facility at least annually.</p> <p>If online training is approved by the facility, it is necessary for the facility to provide additional training regarding action to be taken in the event of exposure specific to their facility.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review personnel files.</li> </ul>	<p>Enter observations of non-compliance, comments, or notes here.</p> <p>.</p>
11-I-3	Each personnel record has evidence of annual universal precaution training.		<p><b>Interpretive Guidance:</b></p> <p>This standard does not apply to administrative staff.</p> <p>Training may be in person or online.</p> <p>Online training courses approved by the facility are acceptable if permitted by facility policy. The facility reviews these courses for appropriateness and approves them at least annually.</p> <p><b>Evaluating Compliance:</b></p> <ul style="list-style-type: none"> <li>Review personnel files.</li> </ul>	<p><input type="checkbox"/> Compliant</p> <p><input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

## SECTION 14: RURAL HEALTH CLINIC (RHC)

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION A: Compliance with Federal, State and Local Laws</b>				
<b>14-A-1</b>	The rural health clinic and its staff are in compliance with applicable Federal, State, and local laws and regulations.	491.4 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.  .
<b>14-A-2</b>	The rural health clinic is licensed pursuant to applicable State and local law.	491.4(a) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-A-3</b>	The staff of the rural health clinic are licensed, certified or registered in accordance with applicable State and local laws.	491.4(b) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION B: Location of Clinic</b>				
<b>14-B-1</b>	Location of clinic.	491.5 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-B-2</b>	The rural health clinic may be a permanent or mobile unit.	491.5(a)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-B-3</b>	If the clinic is a permanent structure, the objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure.	491.5(a)(3)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-B-4	If the clinic is a mobile unit, the objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure, which has fixed, scheduled location(s).	491.5(a)(3)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-B-5	If the clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic.	491.5(a)(3)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>SUB-SECTION C: Physical Plant and Environment</b>				
14-C-1	Physical Plant and Environment	491.6 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-C-2	The clinic is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.	491.6(a) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-C-3	The clinic has a preventive maintenance program to ensure that all essential mechanical, electric and patient-care equipment is maintained in safe operating condition.	491.6(b) Standard  491.6(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-C-4	The clinic keeps the drugs and biologicals appropriately stored.	491.6(b)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-C-5	The clinic premises are kept clean and orderly.	491.6(b)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION D: Organizational Structure</b>				
14-D-1	Organizational Structure.	491.7 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-D-2	The clinic is under the medical direction of a physician, and has a healthcare staff that knows and meets the basic requirements of QUAD A Section 14-D.	491.7(a)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-D-3	The clinic organizational policies and lines of authority and responsibilities are clearly set forth in writing.	491.7(a)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-D-4	The clinic clearly discloses the names and addresses of its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A–3).	491.7(b) Standard  491.7(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-D-5	The clinic has clearly disclosed the name and address of the person principally responsible for directing the operation of the clinic.	491.7(b)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-D-6	The clinic has clearly disclosed the name and address of the person principally responsible for medical direction of the clinic.	491.7(b)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION E: Staffing and Staff Responsibilities</b>				
<b>14-E-1</b>	<b>Physician</b> - As it pertains to the supervision, collaboration, and oversight requirements in sections 1861 (aa)(2)(B) and (aa)(3) of the Social Security Act; a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and - Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Social Security Act for specific limitations). -	491.2 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-2	<p>Nurse practitioner means a person who meets the applicable State's requirements governing the qualifications of nurse practitioners, and who meets at least one of the following conditions:</p> <p>(1) Is certified as a primary care nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice; or</p> <p>(2) Has satisfactorily completed a formal 1 academic year educational program that:</p> <p>(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;</p> <p>(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and</p> <p>(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or</p> <p>(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.</p>	491.2 Condition	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<p><input type="checkbox"/> Compliant</p> <p><input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-3	<b>Physician assistant</b> <ul style="list-style-type: none"> <li>- The Physician assistant meets the applicable State requirements governing the qualifications for assistants to primary care physicians.</li> <li>- The Physician assistant is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or</li> <li>- The Physician assistant has satisfactorily completed a program for preparing physician's assistants that was at least one academic year in length.</li> <li>- The Physician assistant has satisfactorily completed a supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care.</li> <li>- The Physician assistant has satisfactorily completed a supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care which was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.</li> <li>- The Physician assistant has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.</li> </ul>	491.2 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-4	Staffing and staff responsibilities.	491.8 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-5	The clinic has health care staff that includes one or more physicians, and one or more physician's assistants or nurse practitioners.	491.8(a)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-6	The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic, or under agreement with the clinic to carry out the responsibilities required under QUAD A Section 14-D.	491.8(a)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-7	The physician assistant, nurse practitioner, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist or mental health counselor member of the staff may be the owner, an employee of the clinic, or may furnish service under contract to the clinic. At least one physician assistant or nurse practitioner must be an employee of the clinic.	491.8(a)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-8	The clinic staff may include ancillary personnel who are supervised by the professional staff.	491.8(a)(4) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-9	The clinic staff is sufficient to provide essential services for the operation of the clinic.	491.8(a)(5) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-10	There is a physician, certified nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor available to furnish patient care services at all times the clinic operates. In addition, for RHCs, a certified nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.	491.8(a)(6) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-11	The clinic physician provides medical direction for the clinic's health care activities and consultation for, and medical supervision of, the health care staff.	491.8(b) Standard  491.8(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-12	The clinic physician in conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's written policies and services provided to Federal program patients.	491.8(b)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-13	The clinic physician periodically reviews the clinic's patient records, provides medical orders, and provides medical patient care services to the patients of the clinic.	491.8(b)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-14	The physician assistant and the nurse practitioner members of the clinic's staff participate in the development, execution and periodic review of the written policies governing the services the clinic furnishes.	491.8(c) Standard  491.8(c)(1) Standard  491.8(c)(1)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-15	The physician assistant and the nurse practitioner members of the clinic's staff participate with a physician in a periodic review of the patient's health records.	491.8(c)(1)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-16	The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician: Provides services in accordance with the clinic's policies.	491.8(c)(2) Standard  491.8(c)(2)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-17	The physician assistant or nurse practitioner perform the following functions, to the extent they are not being performed by a physician: arranges for, or refers patients to, needed services that cannot be provided at the clinic.	491.8(c)(2)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-18	The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician: assure that adequate patient health records are maintained and transferred as required when patients are referred.	491.8(c)(2)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-20	Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at <u>§ 410.77(a) of this chapter.</u>	491.2 Condition	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><u>SOM (cms.gov) Appendix G</u></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-21	Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of <u>§ 410.71(d) of this chapter.</u>	491.2 Condition	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><u>SOM (cms.gov) Appendix G</u></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-22	Clinical social worker means an individual who meets the applicable education, training, and other requirements at <u>§ 410.73(a) of this chapter.</u>	491.2 Condition	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><u>SOM (cms.gov) Appendix G</u></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-E-23	Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at <u>§ 410.53 of this chapter.</u>	491.2 Condition	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><u>SOM (cms.gov) Appendix G</u></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-E-24	Mental health counselor means an individual who meets the applicable education, training, and other requirements at <a href="#">§ 410.54 of this chapter.</a>	491.2 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>SUB-SECTION F: Provision of Services</b>				
14-F-1	Provision of services.	491.9 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-2	All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws.	491.9(a) Standard  491.9(a)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-F-3	The clinic is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.	491.9(a)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-4	The clinic's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State Law.	491.9(b) Standard  491.9(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-5	The clinic's policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners, and at least one member that is not a member of the clinic staff.	491.9(b)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-6	The clinic's policies include a description of the services the clinic furnished directly and those furnished through agreement or arrangement.	491.9(b)(3) Standard  491.9(b)(3)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-F-7	The clinic's policies include guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.	491.9(b)(3)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-8	The clinic's policies include rules for the storage, handling, and administration of drugs and biologicals.	491.9(b)(3)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-9	The clinic's policies are reviewed at least biennially by the group of professional personnel identified in standard 14-E-4 and reviewed as necessary by the RHC.	491.9(b)(4) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-10	The clinic staff furnish those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system including medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.	491.9(c)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-F-11	The clinic provides laboratory services which implements the provisions of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient.	491.9(a)(4) Standard  491.9(c)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-12	The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including chemical examinations of urine by stick or tablet method or both (including urine ketones).	491.9(a)(4) Standard  491.9(c)(2)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-14	The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including blood glucose.	491.9(a)(4) Standard  491.9(c)(2)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-F-16	The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including pregnancy tests.	491.9(a)(4) Standard  491.9(c)(2)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-17	The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including the collection of patient specimens for transmittal to a certified laboratory for culturing.	491.9(a)(4) Standard  491.9(c)(2)(iv) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-18	The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biological commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.	491.9(c)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-F-19	The clinic has current agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including inpatient hospital care.	491.9(d) Standard  491.9(d)(1) Standard  491.9(d)(1)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-20	The clinic has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere).	491.9(d)(1)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-21	The clinic has current agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to patients including additional and specialized diagnostic and laboratory services that are not available at the clinic.	491.9(d)(1)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-F-22	If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated.	491.9(d)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

14-F-23	The RHC must provide primary care services.	491.9(a)(3)	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><u>SOM (cms.gov) Appendix G</u></p>	<p><input type="checkbox"/> Compliant</p> <p><input type="checkbox"/> Deficient</p> <p>Enter observations of non-compliance, comments, or notes here.</p>
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ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION G: Patient Clinical Records</b>				
<b>14-G-1</b>	Patient health records.	491.10 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-G-2</b>	The clinic maintains a clinical record system in accordance with written policies and procedures.	491.10(a) Standard  491.10(a)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-G-3</b>	The clinic has a designated member of the professional staff who is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.	491.10(a)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-G-4	For each patient receiving health care services, the clinic or center maintains a record that includes identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient.	491.10(a)(3) Standard  491.10(a)(3)(i) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-5	For each patient receiving health care services, the clinic or center maintains a record that includes reports of physical examinations, diagnostic and laboratory test results, and consultative findings.	491.10(a)(3)(ii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-6	For each patient receiving health care services, the clinic or center maintains a record that includes all physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress.	491.10(a)(3)(iii) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-7	For each patient receiving health care services, the clinic or center maintains a record that includes signatures of the physician or other health care professional.	491.10(a)(3)(iv) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.



ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-G-8	The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.	491.10(b) Standard  491.10(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-9	The clinic has written policies and procedures in place that govern the use and removal of records from the clinic and the conditions for release of information.	491.10(b)(2) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-10	The clinic has written policies and procedures in place requiring the patient's written consent for release of information not authorized to be released without such consent.	491.10(b)(3) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
14-G-11	The clinic has written policies and procedures in place for retention of records to be retained for at least six (6) years from date of last entry, and longer if required by State statute.	491.10(c) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
<b>SUB-SECTION H: Program Evaluation</b>				
<b>14-H-1</b>	Program evaluation.	491.11 Condition	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-H-2</b>	The clinic has carried out, or arranged for, a biennial evaluation of its total program.  Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.	491.11(a) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.
<b>14-H-3</b>	The clinic conducts an evaluation, including a review of the utilization of clinic services, including at least the number of patients served and the volume of services.  Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.	491.11(b) Standard  491.11(b)(1) Standard	<b>Interpretive Guidance:</b>  <b>Evaluating Compliance:</b>  <a href="#">SOM (cms.gov) Appendix G</a>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient  Enter observations of non-compliance, comments, or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-H-4	<p>The clinic conducts an evaluation, including a representative sample of both active and closed clinical records.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	491.11(b)(2) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>
14-H-5	<p>The clinic conducts an evaluation, including a review of the clinic's health care policies.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	491.11(b)(3) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>
14-H-6	<p>The clinic conducts an evaluation to determine whether the utilization of services were appropriate.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	<p>491.11(c) Standard</p> <p>491.11(c)(1) Standard</p>	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
14-H-7	<p>The clinic conducts an evaluation to determine whether the established policies were followed.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	491.11(c)(2) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>
14-H-8	<p>The clinic conducts an evaluation to determine whether any changes are needed.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	491.11(c)(3) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>
14-H-9	<p>The clinic staff considers the findings of the evaluation and has taken correct action if necessary.</p> <p>Compliance Note: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation.</p>	491.11(d) Standard	<p><b>Interpretive Guidance:</b></p> <p><b>Evaluating Compliance:</b></p> <p><a href="#">SOM (cms.gov) Appendix G</a></p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <p>Enter observations of non-compliance, comments, or notes here.</p>

## GLOSSARY

**Adequate** is meant to encompass size, space, maintenance, cleanliness, free of clutter, lighting, appropriately equipped, etc.

**Direct Services** means services provided by the clinic's staff. [42 CFR 491.2]

**Rural area** means an area that is not delineated as an urbanized area by the Bureau of the Census. [42 CFR 491.2]

**Rural health clinic or clinic** means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart. [42 CFR 491.2]

**Secretary** means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

**Shortage area** means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act). [42 CFR 491.2]

## **GENERAL GLOSSARY**

**Adequate:** Satisfactory or acceptable in quality or quantity, encompassing size, space, maintenance, cleanliness, freedom from clutter, lighting, equipment, and supplies, etc.; it is meant to satisfy a requirement.

**Advanced Cardiac Life Support (ACLS):** A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in adults that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)*. The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

\*\*\* **Advanced practice registered nurses (APRNs):** Licensed registered nurses educated at a master's or doctoral level and in a specific role and patient population. APRNs are prepared with specialized education and certification to assess, diagnose, and manage medical issues. They can also order tests and prescribe medications. APRNs include:

- 1) Certified registered nurse anesthetist (CRNA).
- 2) Certified nurse practitioner (CNP).
- 3) Clinical nurse specialist (CNS).
- 4) Certified nurse midwife (CNM).

**Adverse event:** An incident in health care that causes unintended harm to patients or providers and is often preventable. Common adverse events include but are not limited to, medication errors, surgical mistakes, infections acquired in healthcare settings, falls, pressure ulcers, and communication failures. All adverse events that occur within 30 (thirty) days of the procedure must be reported to QUAD A contemporaneously when the facility learns of the event.

**Air Exchanges Per Hour (ACH):** The number of times that the total air volume in a room or space is completely removed and replaced in an hour.

**Ambulatory Health Care vs Business Occupancy** [https://cdn.ymaws.com/nehes.site-ym.com/resource/resmgr/presentations/2018/doc\\_presentation\\_cable081718.pdf](https://cdn.ymaws.com/nehes.site-ym.com/resource/resmgr/presentations/2018/doc_presentation_cable081718.pdf)

\*\*\* **Ambulatory surgical center (ASC):** 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 416.2. [42 CFR 416.2]

**Ambulatory Services:** for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures. [42 CFR 416.2]

**Anesthesia professional:** A physician anesthesiologist, Certified Registered Nurse anesthetist (CRNA), Certified Anesthesiologist Assistant (CAA), and an appropriately credentialed Oral and Maxillofacial Surgeon.

\*\* **Antisepsis:** The application of an antimicrobial chemical to the skin or mucous membrane to

reduce the microbial population.

**\*\* Antiseptic:** An agent used for antiseptics (to kill microorganisms or substantially inhibit their growth).

**\*\* Autoclave:** A common term applied to the performance of steam sterilization under pressure, where bacteria are killed (including spores).

**\*\*\* Appropriate/appropriately** means especially suitable or compatible; or fitting.

*Examples:*

- Administrative and patient care areas must have lighting to see all tasks fully.
- Laryngoscopes are cleaned according to the manufacturer's recommendations, though sterilization is preferred.
- Oxygen delivery should be tailored to the appropriate delivery method based on patient need and type/location of the procedure.

**Auxiliary Staff:** Unlicensed staff who are not state-certified/licensed to independently evaluate patient physical status and cannot legally provide emergency duties beyond Basic Life Support for Healthcare Providers. Auxiliary staff includes dental assistants, registered/certified dental assistants, dental anesthesia/sedation assistants, medical assistants, surgical technicians, and other non-independently Licensed Providers.

**Basic Life Support (BLS):** A course that trains and certifies participants to promptly recognize several life-threatening emergencies, give high-quality chest compressions, deliver appropriate ventilations, and provide early use of an automatic external defibrillator (AED) through both didactic and hands-on skills return demonstration sessions. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)* and is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

**\*\* Biological Indicator (BI):** A sterilization process monitoring device commercially prepared with a known population of highly resistant spores that tests the effectiveness of the sterilization method being used. The indicator is used to demonstrate that the conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.

**Business Associate Agreement (BAA):** A contract between the facility and an external business or individual that performs certain functions or activities on behalf of, or provides a service to, the facility when the function, activity, or service involves the creation, receipt, maintenance, or transmission of Protected Health Information (PHI) by the business or individual. The agreement establishes the permissible uses and disclosures of PHI by the business associate, how the business associate will support patients' Privacy Rule rights, and the responsibilities of both parties to maintain the privacy and security of PHI. The Health Insurance Portability and Accountability Act (HIPAA) Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information.

**\*\*\* Certified Anesthesiologist Assistant (CAA):** A master's degree level non-physician anesthesia care provider that:

- 1) Is certified by the National Commission for Certification of Anesthesiologist Assistants (NCAA) Note: not a CMS requirement
- 2) Works under the direction of an anesthesiologist.

- 3) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and
- 4) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—
  - a) Is accredited by the Committee on Allied Health Education and Accreditation; and
  - b) Includes approximately two (2) years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

**\*\*\* Certified Registered Nurse Anesthetist (CRNA):** An advanced practice registered nurse (APRN) who administers anesthesia and other medications. Physician Supervision (either the operating practitioner or of an anesthesiologist who is immediately available if needed) is required if required by state or federal law.

- 1) Is licensed as a registered professional nurse by the State in which the nurse practices.
- 2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists.
- 3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and
- 4) Meets the following criteria:
  - (i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or
  - (ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.
- 5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

**\*\* Chemical Indicator (CI):** A sterilization monitoring device used to monitor the attainment of one (1) or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.

**\*\*\*Clinic:** A facility (Rural Health Clinic (RHC)) that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

- The medical services are furnished by a group of three or more physicians practicing medicine together.
- A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services. **[485.703 Condition]**

**\*\*\*Clinic Administrator:** The individual responsible for the internal operation of the RHC in accordance with written policies. A qualified Clinic Administrator is designated by the facility's governing body. **[CMS §485.705(c)(1) and §485.709(b)]**

**\*\*\* Clinical Personnel:** The entire clinical team providing services in the facility, including, but not limited to, all physicians/surgeons/proceduralists, anesthesia providers, nurses, scrub techs, physician assistants, physical/occupational/speech therapists and assistants, social workers, clinical psychologists, marriage and family therapists, mental health counselors, medical assistants,



etc. Employment status (owner, employee, contractor, contracted, indirect employee, prn staff, etc.) is not a factor in defining who is included as Clinical Personnel.

\*\*\* **Covered ancillary services:** items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. **[42 CFR 416.2]**

\*\*\* **Covered surgical procedures:** surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. **[42 CFR 416.2]**

\*\* **Contact Time:** "Wet time," also known as "contact time" or "dwell time," is the amount of time a disinfectant or antiseptic solution must remain wet and in direct contact with a target microorganism or on a surface to be effective. This time can range from 15 seconds to 10 minutes, which is the maximum time allowed by the US Environmental Protection Agency (EPA). The contact time is established by the product manufacturer.

\*\* **Contamination:** The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.  
Contemporaneously: Originating, existing, or happening during the same period of time.

**Continual:** Repeated regularly and frequently in steady, rapid succession.

**Continuous:** Prolonged without interruption at any time.

**Contract & Indirect Employees:** These employees are not on the company's payroll and are not restricted by employment laws that apply to direct employees. Work details are defined in a contract agreed upon by the company and a contractor or third-party agency.

\* **Deep Sedation/Analgesia:** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Decontamination: Any physical or chemical process that reduces the number of microorganisms on any inanimate object to render that object safe for subsequent handling.

**Dental Anesthesiologist:** A licensed DDS or DMD with specialized, hospital-based training in areas including pharmacology, internal medicine, emergency medicine, and pediatric and adult anesthesiology.

**Dental Assistant:** A dental team member who supports a dental operator in providing more efficient dental treatment. A dental assistant must graduate from an accredited dental assisting training program and earn certification or licensure as State law requires.

**Direct Employee:** A full- or part-time employee hired by a facility and paid directly through the facility's payroll. They are considered permanent employees because the intention is to work with them long-term rather than temporarily or as needed.

\*\*\***Direct Services** means services provided by the clinic's staff. **[42 CFR 491.2]**

**\*\* Disinfectant:** A chemical agent used to kill viruses and bacteria on surfaces. It must be an EPA-registered disinfectant with bactericidal, tuberculocidal, and virucidal properties with specific claims and instructions for HIV and HBV.

**\*\* EPA-Registered:** An EPA registration number signifies that a disinfectant and its claims have been reviewed and approved by the United States Environmental Protection Agency.

**\*\*\*Extension Location:** A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency. **[485.703 Condition]**

**Facility Director:** An individual that manages all aspects of a facility's operations. Their duties include budget management, facility planning, and building system maintenance.

**Facility Leadership and Governing Body:** These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

**Facility Safety Manual:** A compilation of safety procedures and guidelines to follow in emergencies or unsafe situations.

**\*\*\* Facility services:** for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure. **[42 CFR 416.2]**

**General Anesthesia:** A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

**Governing Body and Facility Leadership:** These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

**\*\* Healthcare-Associated Infection (HAI):** An infection acquired by patients while they are receiving medical care, with confirmation of diagnosis by clinical or laboratory evidence. Infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the healthcare setting.

**\*\* Immediate Use Steam Sterilization (IUSS):** An abbreviated process of steam sterilization of patient care instruments (or devices) for immediate use.

**Immediately Available:** Accessible (clinician and equipment) without any delay or waiting period. Examples include the physical presence of the health care professional in the facility to assess, evaluate, and provide care to a patient; a supervising physician is physically accessible and able to attend to the patient, without any delay, to address any situation requiring a supervising physician's services; and, 1) dedicated to the facility when on duty, 2) unencumbered by conflicting duties or responsibilities, 3) responding without delay when notified.

**\*\*Infection:** The invasion and multiplication of microorganisms in body tissues that cause cellular injury and clinical symptoms.

**Intraoperatively:** The intraoperative phase extends from the time the patient is admitted to the operating room to the time of anesthesia administration, the performance of the surgical procedure, and until the client is transported to the recovery room or post-anesthesia care unit (PACU).

**\*\* Instructions for Use (IFUs):** Specific, detailed instructions provided by the manufacturer. IFUs for medical devices detail the steps required for cleaning, disinfection, and sterilization that are compatible with that device. Products approved for use in cleaning, disinfection, and sterilization will have specific IFUs to follow (e.g., dilution ratio and contact time) to ensure the product's efficacy.

**Legally Qualified:** Being in compliance or accordance with specific requirements or conditions. Is qualified under the applicable local, State or Federal law to hold the position for which he or she holds and has met the qualifications of the position.

**Log:** A written record of performance, events, or day-to-day activities. It is similar to a register, which is a written record containing regular entries of items or details.

*Examples:*

- On any day that controlled substances are administered, the controlled substance inventory and control record (log/register) must be updated as appropriate to reflect controlled substances administered, received, wasted, and currently stored by two licensed healthcare professionals. (6-D-2)
- A written record (log/register) of all operative cases is maintained by the facility. (8-L-1)

**\*\* Mechanical (Physical) Indicator:** Monitors (embedded into the sterilization equipment) that register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence the sterilization system has met the set parameters (or has not, and there is a need for corrective action).

**Medical Director:** The clinician responsible for overall oversight of the facility.

**\*\*\* Medical Staff:** The organized body of licensed physicians and other healthcare providers who are permitted by law and through credentialing and privileges granted by the facility leadership to provide medical care within the facility. The medical staff includes physicians, surgeons, specialists, CRNAs, NPs, PAs, and allied health professionals, as identified in facility policy.

**\* Minimal Sedation:** A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

\* **Moderate Sedation/Analgesia (“Conscious Sedation” or “Procedural Sedation”)**: A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

\* **Monitored Anesthesia Care (“MAC”)** does not describe the continuum of depth of sedation; rather, it describes “a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure.” Indications for monitored anesthesia care include “the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic).

#### **National Fire Protection Association (NFPA) Business Occupancies, 2021**

<https://www.nfpa.org/news-blogs-and-articles/blogs/2021/05/07/occupancy-classifications-and-model-codes>

- 1) **Business Occupancy** is an occupancy used for the transaction of business other than mercantile (engaged in commerce) This includes clinics.
- 2) **Ambulatory Health Care Occupancies** are occupancies used to provide services or treatment simultaneously to four or more patients that provide, on an outpatient basis, one or more of the following:
  - a. Treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others
  - b. Anesthesia that renders patients incapable of taking action for self-preservation under emergency conditions without the assistance of others
  - c. Emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others

Examples include Day Surgery, Dentists' Offices, oral surgery with sedation, and Endoscopy Centers.

\*\*\* **Nurse Practitioner (NP)**: A person who is currently licensed to practice in the State and meets the applicable State requirements governing the qualifications of nurse practitioners. And meets at least one (1) of the following conditions:

- 1) Is certified as a practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice or
- 2) Has satisfactorily completed a formal one (1) academic year educational program that:
  - i. Prepares registered nurses to perform an expanded role.
  - ii. That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.
  - iii. Awards a degree, diploma, or certificate to persons who successfully complete the program.
- 3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role) that does not meet the requirements identified above in paragraph 2, and the Nurse Practitioner has been performing an expanded role in the delivery of care for a total of 12 months during the 18-month period immediately preceding the effective date of the subpart.

**Nurses Note:** Documentation that provides a record of nursing care provided to a patient, family, or community.

**Oral Maxillofacial Surgeon (OFM):** A medical doctor who is specifically trained in maxillofacial surgery. Because of the focus on the oral area, typically, maxillofacial surgeons attend dental school for four years after receiving their bachelor's degree.

**Patient Safety Data Reporting (PSDR):** A form of quality control performed by QUAD A accredited facilities within the outpatient setting. Those participating in the data reporting process create a system-wide culture of clinical quality and demonstrate the positive results of accreditation. PSDR reporting is required for QUAD A facilities participating in Office-Based Surgical, Office-Based Procedural, Oral Maxillofacial Surgery, Pediatric Dentistry, International Surgical, or Medicare ASC programs. Reporting PSDR data is required quarterly, including physician case review. Results of the physician case reviews are discussed during Peer Review meetings.

**Pediatric Advanced Life Support (PALS):** A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in children that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)*. The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

**Pediatric Dentist:** A licensed dentist in the state where the dentist practices and who has satisfactorily completed:

- 1) Four (4) years of dental school.
- 2) Two (2) additional years of residency training in dentistry for infants, children, teens, and children with special needs.
- 3) A minimum of 24 months in an advanced education program accredited by the Commission on Dental Accreditation of the American Dental Association. Such programs "must be designed to provide special knowledge and skills beyond the Doctor of Dental Surgery (DDS) or Doctor of Medicine in Dentistry (DMD) training.
- 4) A curriculum of an advanced program provides the dentist with the necessary didactic background and clinical experiences to provide comprehensive primary oral health care and the services of a specialist.

**\*\* Peel Pouch:** A sterilization pouch (or peel pack) is a disposable package validated for use in a sterilizer to allow penetration of the sterilant to the items placed inside. After sterilization, peel pouches maintain the sterility of the processed item(s) during storage and until needed for use. Pouches are designated as Class II medical devices and may be self-sealing or heat-sealing. "Double pouching" should only be performed if validated for the specific type of pouch and when the manufacturer's instructions for use provide the method of packaging and the sterilization parameters.

**Peer:** An individual(s) of the same professional discipline and specialty who possesses sufficient training and experience to render judgment on the clinical circumstances under review.

**Peer Review:** The task of physicians holding one another to the ethical standards of their profession and maintaining the administration of patient safety and quality of care consistent with optimal standards of practice. The American Medical Association (AMA) publishes information regarding the peer review process and describes the composition of the Peer Review Committee as follows:

*Peer review is conducted in good faith **by physicians who are within the same***

***geographic area or jurisdiction and medical specialty of the physician subject to review*** to ensure that all physicians consistently maintain optimal standards of competency to practice medicine. Physicians outside of the organization that are convening peer review may participate in that organization's peer review of a physician if the reviewing physician is within the same geographic area or jurisdiction and medical specialty as the physician who is the subject of peer review.

What is Peer Review? <https://www.amwa-doc.org/what-is-peer-review/>

**Personnel:** Everyone employed (including volunteers) at a facility, including both direct and indirect (contract) employees who provide care, treatment, or services to patients. The terms “personnel” and “staff” are synonymous.

**\*\* Personal Protective Equipment (PPE):** Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury and minimize exposure to hazards.

**\*\*\* Physician:** Providers who medically diagnose patients, prescribe and manage medication, and supervise other medical staff A licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO) legally authorized to practice medicine or surgery in the State in which the function is performed; and a Doctor of Dental Surgery (DDS) or Doctor of Dental Medicine (DMD) who is legally authorized to practice dentistry by the State in which he/she performs such function and who is acting within the scope of his/her license and a Doctor of Podiatric Medicine

**Physician Anesthesiologist:** A medical doctor who has attained either a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO) degree and has chosen to specialize in the field of anesthesiology and specializes in anesthesia care, pain management, and critical care medicine, and have the necessary knowledge to understand and treat the entire human body.

**\*\*\* Physician Assistant (PA):** An individual who meets the applicable State requirements governing the qualifications for assistants to primary care physicians. And meets one of the following conditions:

- 1) The physician assistant is currently certified by the National Commission on Certification of Physician Assistants to assist physicians.
- 2) The physician assistant has satisfactorily completed a program for preparing physician's assistants that:
  - i. Was at least one (1) academic year in length.
  - ii. Consisted of supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and
  - iii. Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.
- 3) The physician assistant has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.
- 4) Is licensed as a PA by the State in which the PA practices.

**Proceduralist:** A licensed physician, usually a specialist or subspecialist, trained and qualified to perform diagnostic or therapeutic procedures. A licensed and trained CRNA and PA may also conduct selected procedures based on state law and scope of practice.

**Procedural accreditation:** This is intended for office-based facilities performing procedures in medical specialties including gastroenterology, urology/nephrology, gynecology, interventional radiology/vascular access, pain management, and dermatology. Procedures are performed by specialists including Gastroenterologists, Urologists/Nephrologists, Gynecologists, Pain Management Specialists, Dermatologists, or Interventional Radiologists/Vein Specialists, and may include minimally invasive procedures and approved minor surgical procedures (e.g. minor urological surgical procedures including circumcisions, vasectomies; minor dermatological procedures including mole/growth removal, minimally invasive gynecological surgeries as entered through the vagina, etc.).

**Progress note:** An essential tool used in healthcare to document patient information, medical history, treatment plans, and progress throughout a patient's care. Progress notes are also a crucial communication tool among healthcare professionals, ensuring continuity of care and facilitating collaboration.

**Public health agency:** an official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services. **[485.703 Condition]**

**Qualified:** An individual who is qualified by education, training, licensure/regulation (when applicable, also includes registration and certification), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

**Rehabilitation agency -**

An agency that:

- Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
- Provides at least physical therapy or speech-language pathology services.

**[485.703 Condition]**

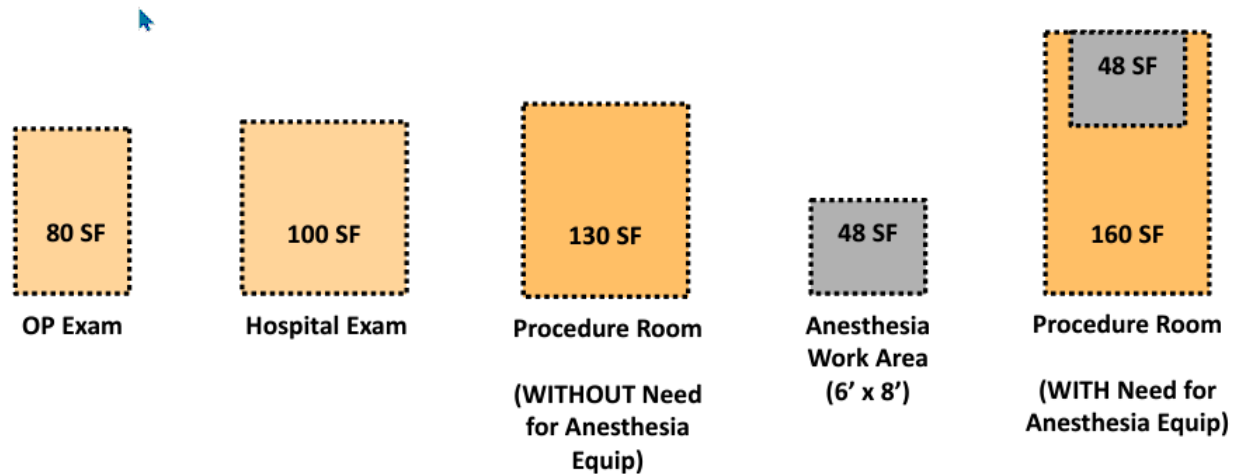


\*\*\*\* Room Classifications:

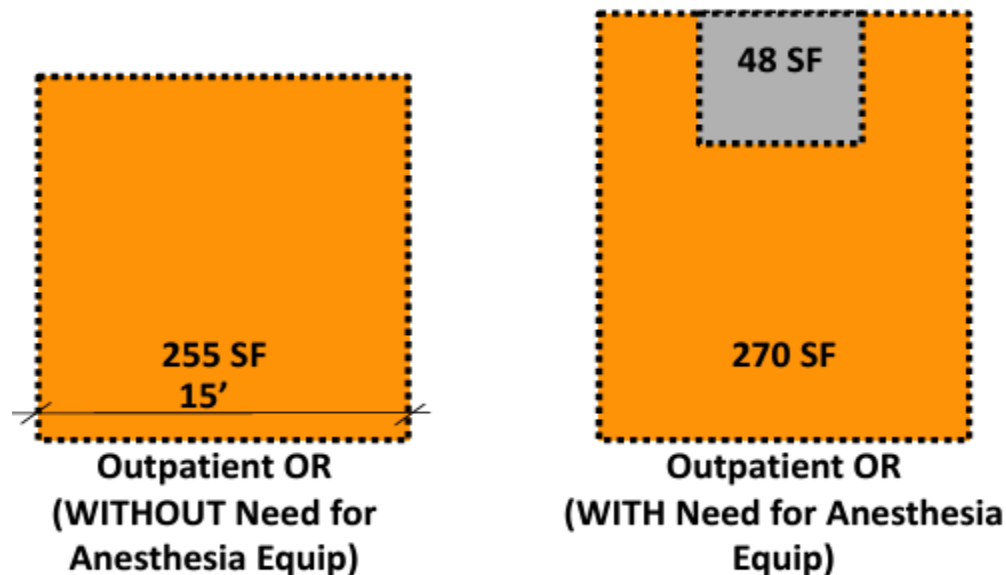
Room Type	Use	Environmental Controls		
		Location	Ventilation (excerpted from ASHRAE 170)	Surfaces
Exam Room or Treatment Room	Patient care that may require high-level disinfection or sterile instruments but does not require the environmental controls of a procedure room	Accessed from an unrestricted area	<p>4 total ACH for general exam room</p> <p>6 total ACH for exam rooms programmed for use by patients with undiagnosed gastrointestinal symptoms, respiratory symptoms, or skin symptoms</p> <p>No pressure requirement</p> <p>Standard diffuser and return array</p>	<p>Ceilings: Cleanable with routine housekeeping equipment</p> <p>Floor: No special requirement</p> <p>Walls: No special requirement</p>
Procedure Room	Patient care that requires high-level disinfection or sterile instruments and some environmental controls but does not require the environmental controls of an operating room	Accessed from an unrestricted or a semi-restricted area	<p>15 ACH / Positive pressure</p> <p>Standard diffuser and return array</p>	<p>Ceilings: Smooth and without crevices, scrubbable, non-absorptive, non-perforated; capable of withstanding cleaning chemicals; without crevices; lay-in ceiling permitted if gasketed or each ceiling tile weighs at least one pound per square foot and no perforated, tegular, serrated, or highly textured tiles. Lay-in ceiling permitted if gasketed or each ceiling tile weighs at least 1lb/SF</p> <p>Floor and wall base assemblies for cystoscopy, urology, and endoscopy procedure rooms: Monolithic with an integral coved wall base that is carried up the wall a minimum of 6'</p> <p>Wall finishes for endoscopy: Free of fissures, open joints, or crevices that may retain or permit passage of dirt particles</p>
Operating Room	<p>Invasive procedures*</p> <p>Any procedure during which the patient will require physiological monitoring and is anticipated to require active life support</p>	Accessed from a semi-restricted area	<p>20 total ACH / Positive pressure</p> <p>Primary supply diffuser array extend a minimum of 12" beyond the footprint of the surgical table on each side</p> <p>At least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible</p>	<p>Ceilings: Monolithic, scrubbable, capable of withstanding cleaning and/or disinfecting chemicals, gasketed access openings</p> <p>Floor and wall base assemblies: Monolithic with an integral coved wall base that is carried up the wall a minimum of 6'</p> <p>Wall finishes: Free of fissures, open joints, or crevices that may retain or permit passage of dirt particles</p>



## 2018 FGI Guidelines for Minimum Room Sizes: Exam, Treatment & Procedure Rooms



## 2018 FGI Guidelines for Minimum Room Sizes: Operating Rooms



\*\*\* **Rural area** mean an area that is not delineated as an urbanized area by the Bureau of the Census. [42 CFR 491.2]

\*\*\* **Rural health clinic:** a clinic located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases and meets all other requirements of this subpart. [42 CFR 491.2]

\*\*\* **Secretary:** The Secretary of Health and Human Services, or any official to whom he/she has delegated the pertinent authority.

\*\*\* **Shortage area:** a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act). [42 CFR 491.2]

**Staff:** Anyone employed (part-time, full-time) at a facility, including both direct and indirect (contract) employees that provide care, treatment, or services to patients. The terms “personnel” and “staff” are synonymous.

\*\*\* **Direct Services:** services provided by the clinic’s staff. [42 CFR 491.2]

\*\* **Sterile:** The state of being free from all living microorganisms. In practice, it is usually described as a probability function (e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000).

\*\* **Sterilization:** A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability (which, even though is a very low number, may never be zero).

**Surgeon:** A physician trained and qualified to perform surgical procedures.

\*\*\* **Surgery** is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous when ordered by a physician.) Surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

- 1) **Major surgery** is an invasive operative procedure where one (1) or more of the following occurs:
  - a. A body cavity is entered.
  - b. A mesenchymal barrier is crossed.
  - c. A fascial plane is opened
  - d. An organ is removed
  - e. Normal anatomy is operatively altered
- 2) **Minor Surgery** is an invasive operative procedure in which only skin, mucous membranes, or superficial connective tissue is manipulated.

\*\*\* **Supervision**

1. **Direct Supervision:** The supervising physician must be immediately available if needed, meaning physically present in the facility, and prepared to immediately conduct hands-on intervention if needed. However, the physician does not need to be in the room throughout the performance of the service.
2. **General supervision:** The service is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who

actually perform the diagnostic procedure and maintain the necessary equipment and supplies is the physician's continuing responsibility.

**3. Personal supervision:** A physician must be present in the room during the procedure.

**\* Surgical Site Infection (SSI):** An infection at the site of a surgical incision. The SSI may be superficial, deep, or extend to organs. Patients should be monitored for SSIs for thirty (30) days after surgery or procedures or three-hundred and sixty-five (365) days after implant placement.

## Ventilation of Health Care Facilities. ASHRAE/ASHE standard 170-2008

**TABLE 7-1 Design Parameters**

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	RH (k), %	Design Temperature (l), °F/°C
<b>SURGERY AND CRITICAL CARE</b>							
Class B and C operating rooms, (m), (n), (o)	Positive	4	20	N/R	No	20-60	68-75/20-24
Operating/surgical cystoscopic rooms, (m), (n), (o)	Positive	4	20	N/R	No	20-60	68-75/20-24
Delivery room (Caesarean) (m), (n), (o)	Positive	4	20	N/R	No	20-60	68-75/20-24
Treatment room (p)	N/R	2	6	N/R	N/R	20-60	70-75/21-24
Trauma room (crisis or shock) (c)	Positive	3	15	N/R	No	20-60	70-75/21-24
Laser eye room	Positive	3	15	N/R	No	20-60	70-75/21-24
Class A Operating/Procedure room (o), (d)	Positive	3	15	N/R	No	20-60	70-75/21-24
<b>DIAGNOSTIC AND TREATMENT</b>							
Gastrointestinal endoscopy procedure room	Positive	2	6	N/R	No	20-60	68-73/20-23

## APPENDIX 2

### **Purpose and Scope**

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act). [42 CFR 491.1]

### **Certification Procedures**

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid. [42 CFR 491.3z]

## APPENDIX 3

### Location of Clinic

The location of the rural health clinic meets all basic requirements and is in a rural area that is designated as a shortage area. [42 CFR 491.5, 42 CFR 491.5(a)(1)]

#### Exceptions:

CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area. [42 CFR 491.5(b)(1)]

A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served. [42 CFR 491.5(b)(2)]

Determinations on these exceptions will be made by the Secretary upon application by the facility. [42 CFR 491.5(b)(3)]

#### Criteria for designation of rural areas, as defined by CMS:

Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau. [42 CFR 491.5(c)(1)]

#### Excluded from the rural area classification are:

Central cities of 50,000 inhabitants or more; [42 CFR 491.5(c)(2)(i)]

Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities; [42 CFR 491.5(c)(2)(ii)]

Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban. [42 CFR 491.5(c)(2)(iii)]

Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural. [42 CFR 491.5(c)(3)]

#### Criteria for designation of shortage areas, as defined by CMS:

The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are: [42 CFR 491.5(d)(1)]

The ratio of primary care physicians practicing within the area to the resident population; [42 CFR 491.5(d)(1)(i)]

The infant mortality rate; [42 CFR 491.5(d)(1)(ii)]

The percent of the population 65 years of age or older; [42 CFR 491.5(d)(1)(iii)] and

The percent of the population with a family income below the poverty level. [42 CFR 491.5(d)(1)(iv)]

The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are: [42 CFR 491.5(d)(1)]

The area served is a rational area for the delivery of primary medical care services; [42 CFR 491.5(d)(1)(i)]

The ratio of primary care physicians practicing within the area to the resident population; [42 CFR 491.5(d)(1)(ii)] and

The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area. [42 CFR 491.5(d)(1)(iii)]

A medically underserved population includes the following: [42 CFR 491.5(e)]

A population of an urban or rural area that is designated by PHS as having a shortage of personal health services. [42 CFR 491.5(e)(1)]

A population group that is designated by PHS as having a shortage of personal health services. [42 CFR 491.5(e)]

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