



MEDICARE OUTPATIENT PHYSICAL THERAPY (OPT) ACCREDITATION STANDARDS MANUAL

Version 4.0, Effective April 7, 2025

AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES

Facility: [Company] Facility ID: [Enter ID] Survey End Date: Click or tap to enter a date. Surveyor: [Enter Name]

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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 that states, “Each operating room is properly cleaned, maintained and free of litter and clutter” is the fourth standard under Section 2, Sub-section C. Therefore, the unique identifier for this standard is: 2-C-4.

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 a surveyor observes even one instance of non-compliance, the standard is scored as “Deficient,” and the facility will be required to submit a Plan of Correction and evidence of completed corrections.

There may be an 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 remains uncompromised.

NOTES:

Click or tap here to enter text.

SECTION 1: BASIC MANDATES

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION B: BASIC MANDATES				
1-B-7	Only recognized abbreviations are allowed to be used in the clinical record.	A B C	<p>Interpretive Guidance: 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>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Validate the list of approved abbreviations and resources used, such as MedicineNet Medical Dictionary and Tabers Medical Dictionary, or facility-developed policy. • During clinical record review, note abbreviations used and ensure these are on the official abbreviation list adopted by the facility. 	<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
1-B-8	<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"> 1. A completed Self-Survey checklist 2. A Plan of Correction for any standard identified as non-compliant 3. Evidence that each plan of correction has been carried out to establish compliance with standards 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. 		<p>Interpretive Guidance: The intent is to ensure that the facility performs annual self-surveys consistent with QUAD A requirements.</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Review the most recent self-survey for completeness. Are the required elements present? 	<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>

SUB-SECTION E: QUAD A-MANDATED REPORTING

1-E-3	<p>Any action affecting the current professional license of any licensed staff 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>	<p>A B C</p>	<p>Interpretive Guidance: 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> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> • 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. 	<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>
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ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<ul style="list-style-type: none"> <li data-bbox="1161 232 1646 337">• Review clinical personnel files to determine if there is evidence of such action. <li data-bbox="1161 337 1646 443">• If licensure action has occurred, is there evidence that the action was reported timely to QUAD A? 	

SECTION 2: FACILITY LAYOUT AND ENVIRONMENT

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION B: FACILITY ENVIRONMENT				
2-B-1	The facility must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.	A B C	Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION E: STORAGE				
2-E-3	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.	A B C	Interpretive Guidance: 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 potency. 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. Re-processing "expired" supplies is not acceptable unless the item is implicitly approved for such and the process is	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable <input type="checkbox"/> Corrected Onsite Enter observations of non-compliance, comments or notes here.

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>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>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Inspect and check for expired supplies, instruments, implants and equipment used in the facility. • Check manufacturers' recommendations for accurate best use by date or expirations. • 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. • 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? • Interview staff. 	

SECTION 3: SAFETY

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: MEDICAL HAZARDOUS WASTE				
3-D-1	All medical hazardous wastes (including disposable 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.	A B C	<p>Interpretive Guidelines: The intent is to ensure safe practices when handling medical hazardous wastes.</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Review facility policies and procedures. • Interview staff. • Observe staff handling medical hazardous wastes. <p>CDC Regulated Medical Waste, 2003 https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste</p> <p>EPA Medical Waste, 2024 https://www.epa.gov/rcra/medical-waste</p> <p>OSHA Hazardous Waste https://www.osha.gov/hazardous-waste/standards</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
3-D-4	Used disposable sharp items are placed in secure puncture-resistant containers that are located as close to the use area as is practical.	A B C	<p>Interpretive Guidance: 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"> • Functionality: Containers should be puncture-resistant, durable during installation and transport, and an appropriate size and shape. The closure should be secure and minimize exposure during closure. • Accessibility: 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. • Visibility: 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. • Accommodation: Containers should facilitate ease of storage and assembly, require minimal worker training, be easy 	<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
			<p>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.</p> <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 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</p>	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p>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>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Review facility policy and procedures on the disposal of used sharps. • Are sharps disposal containers puncture-proof? • Are sharps disposal containers secured to prevent accidental tipping of the container? • Observe employees discarding used sharps. • 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?) • Are used sharps disposed of properly? 	

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
			<p data-bbox="1159 289 1629 423">CDC - Bloodborne Infectious Diseases - Stop Sticks : Sharps Disposal - NORA Workplace Safety and Health Topic</p> <p data-bbox="1159 459 1629 594">FDA Sharps Disposal Containers https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers</p> <p data-bbox="1159 630 1646 764">Department of Transportation (DOT) Regulations https://www.hercenter.org/regsandstandards/dot.php</p> <p data-bbox="1159 800 1629 899">NIOSH - Selecting, Evaluating, and Using Sharps Disposal Containers https://stacks.cdc.gov/view/cdc/6386</p> <p data-bbox="1159 935 1629 1070">USDA - Safely Using Sharps https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers</p> <p data-bbox="1159 1105 1629 1268">Sharps Contain Regulations: Your Guide, 2024 https://www.danielshealth.com/knowledge-center/sharps-container-regulations-your-guide</p>	

SECTION 5: IN CASE OF EMERGENCY

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION D: Emergency Preparedness Plan				
5-D-1	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.	485.727 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-2	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.	485.727(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-3	The plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.	485.727(a)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.

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5-D-4	The plan must include strategies for addressing emergency events identified by the risk assessment.	485.727(a)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<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.	485.727(a)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-6	The plan must address the location and use of alarm systems and signals; and methods of containing fire.	485.727(a)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</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
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.	485.727(a)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-8	The plan must be developed and maintained with assistance from fire, safety, and other appropriate experts.	485.727(a)(6) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<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.	485.727(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</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
5-D-11	At a minimum, the policies and procedures must address safe evacuation from the Provider/Supplier.	485.727(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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 care and treatment needs of evacuees.	485.727(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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.	485.727(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
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.	485.727(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<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.	485.727(b)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<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.	485.727(b)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</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
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.	485.727(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
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.	485.727(c)(1) Standard 485.727(c)(1)(i) Standard 485.727(c)(1)(ii) Standard 485.727(c)(1)(iii) Standard 485.727(c)(1)(iv) Standard 485.727(c)(1)(v) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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.	485.727(c)(2) Standard 485.727(c)(2)(i) Standard 485.727(c)(2)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
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.	485.727(c)(3) Standard 485.727(c)(3)(i) Standard 485.727(c)(3)(ii) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-25	The communication plan must include a method for sharing information and medical documentation for patients under the Provider/Supplier's care, as necessary, with other health care providers to maintain the continuity of care.	485.727(c)(4) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf	<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.	485.727(c)(5) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf	<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-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.	485.727(d) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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.	485.727(d)(1)(i) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-31	The training program must provide emergency preparedness training at least every two (2) years.	485.727(d)(1)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
5-D-32	The training program must maintain documentation of all emergency preparedness training.	485.727(d)(1)(iii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-33	The training program must demonstrate staff knowledge of emergency procedures.	485.727(d)(1)(iv) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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.	485.727(d)(1)(v) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
5-D-35	The Provider/Supplier must conduct exercises to test the emergency plan at least annually.	485.727(d)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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>485.727(d)(2)(i) Standard</p> <p>485.727(d)(2)(i)(A) Standard</p> <p>485.727(d)(2)(i)(B) Standard</p>	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
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>485.727(d)(2)(ii) Standard</p> <p>485.727(d)(2)(ii)(A) Standard</p> <p>485.727(d)(2)(ii)(B) Standard</p> <p>485.727(d)(2)(ii)(C) Standard</p>	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</p>	<p><input type="checkbox"/> Compliant <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>485.727(d)(2)(iii) Standard</p>	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf</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
SUB-SECTION E: Emergency Preparedness Plan – Integrated Healthcare System				
5-E-1	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.	485.727(e) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-E-2	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.	485.727(e)(1) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-E-3	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.	485.727(e)(2) Standard	Interpretive Guidance: Evaluating Compliance: CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf	<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.	485.727(e)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-E-6	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, 5-D-6, and 5-D-7.	485.727(e)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</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
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.	485.727(e)(4)(i) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<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.	485.727(e)(4)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
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.	485.727(e)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS Appendix Z: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emerg_prep.pdf</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.

SECTION 7: INFECTION CONTROL

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION B: HAND HYGIENE				
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>	A B C	<p>Interpretive Guidance: 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 ensure 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</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>

		<p>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. 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</p>	
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			<p>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 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>If hand sanitizer is decanted from one container to another, the re-filled container must be labeled with the contents and contain and an expiration date.</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Review the facility's policies and procedures. Are they consistent with the current adopted nationally recognized guidelines and standards of practice adopted by the facility? • Interview staff. Are they knowledgeable of hand hygiene and surgical scrub policies and procedures? • Are surgical scrub products, soap, and alcohol-based hand rubs readily accessible to the operating room staff consistent with current CDC and WHO guidelines for hand hygiene? • Is the hand scrub sink located in the semi-restricted areas near the entrance to the OR or procedure room? 	
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			<ul style="list-style-type: none"> Hand wash sinks must be separate from sinks used to clean dirty instruments. Does the facility have separate sinks for these purposes? Observe practice. <p>Clinical Safety: Hand Hygiene for Healthcare Workers https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html</p> <p>CONSENSUS RECOMMENDATIONS - WHO Guidelines on Hand Hygiene in Health Care - NCBI Bookshelf (nih.gov) https://www.ncbi.nlm.nih.gov/books/NBK144035/#:~:text=When%20performing%20surgical%20hand%20antisepsis,are%20not%20necessary%20(IB)</p> <p>World Health Organization (WHO) https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene</p>	
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SUB-SECTION C: INSTRUMENT PROCESSING

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.	A B C	<p>Interpretive Guidance: 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>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
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			<p>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Review the written policies and procedures for cleaning of all equipment used in patient care. • Interview staff regarding their knowledge of these policies and procedures. • 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, OPT and Speech Language equipment, and endoscopes) cleaned and reprocessed (disinfected or sterilized) prior to use on another patient or when soiled in accordance with manufacturer's instructions for use? • 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 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_351.pdf). 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 not a required form for all facility types. 	
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		<ul style="list-style-type: none"> • Is there a separation between clean and soiled equipment maintained to prevent cross-contamination? • Is the correct use of PPE necessary for the task? • Do personnel responsible for disinfecting patient care equipment have training? • 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)? <p>CDC Recommendations for Disinfection and Sterilization in Healthcare Facilities, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html</p> <p>CDC Disinfection and Sterilization Guideline, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html</p> <p>CDC Disinfection of Healthcare Equipment, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/healthcare-equipment.html</p>	
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SECTION 8: CLINICAL RECORDS

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: GENERAL CLINICAL RECORDS				
8-A-6	Electronic health records (EHR) must comply with security and privacy obligations under current HIPAA regulations.	A B C	<p>Interpretive Guidance: 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>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Does the EHR comply with current HIPAA regulations? • Is the EHR password protected? 	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
8-A-8	Clinical records for each patient must be accurate, legible, and promptly completed.	A B C	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
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.	A B C	<p>Interpretive Guidance: 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>Evaluating Compliance:</p> <ul style="list-style-type: none"> • Interview staff. 	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.

			<ul style="list-style-type: none"> • Are clinical records retained for the number of years required by QUAD A, and state law? The more stringent requirement applies. • What is the process for destroying paper-based records? Who is authorized to destroy clinical records? • 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. 	
8-A-10	Clinical records are maintained and easily accessible by the accredited facility.	A B C	<p>Interpretive Guidance: The intent is to ensure that clinical records are maintained and easily accessible.</p> <p>Clinical records may be in an electronic or paper-based format.</p> <p>Evaluating Compliance: Are clinical records maintained and easily accessible?</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: PRE-OPERATIVE DOCUMENTATION				
8-B-1	Clinical records must contain patient identification.	A B C 485.721(b)	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.

SECTION 11: PERSONNEL

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION E: Facility Staffing				
11-E-6	All qualified personnel practicing in an accredited organization must meet one of the following criteria: - PT - Physical Therapist - PTA - Physical Therapist Assistants - OT - Occupational Therapist - OTA - Occupational Therapist Assistance - SLP - Speech Language Pathologist		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.
SUB-SECTION I: PERSONNEL TRAINING				
11-I-1	Each personnel record has evidence of annual hazard safety training.	A B C	Interpretive Guidance: Exposure to blood borne pathogens is a risk to the employee's health. Bloodborne pathogen training 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. This standard does not apply to administrative staff. Training may be in person or online. Online training courses approved by the facility are acceptable. The facility reviews these courses for appropriateness and approves them at least annually. If online training is approved by the	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.

			<p>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>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review personnel files. 	
11-I-2	Each personnel record has evidence of annual blood borne pathogen training.	A B C	<p>Interpretive Guidance: Exposure to blood borne pathogens is a risk to the employee’s health. Bloodborne pathogen training 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. The facility reviews these courses for appropriateness and approves them 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>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review personnel files. 	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient <input type="checkbox"/> Not Applicable Enter observations of non-compliance, comments or notes here.

<p>11-I-3</p>	<p>Each personnel record has evidence of annual universal precaution training.</p>	<p>A B C</p>	<p>Interpretive Guidance: 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>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review personnel files. 	<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>

SECTION 15: OUTPATIENT PHYSICAL THERAPY (OPT)

ID	Standard	CMS Ref	Interpretive Guidance	Score/Findings/Comments
SUB-SECTION A: Personnel Qualifications				
15-A-1	Except as specified in paragraphs 15-A-2 through 15-A-13 of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.	485.705 Condition 485.705(a) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)A Interpretive Guidance: Evaluating Compliance: Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-2	Federally defined qualifications must be met: For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in 42 CFR 484.	485.705(b) Standard 485.705(b)(1) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-A-3	Federally defined qualifications must be met: For a speech-language pathologist, the qualifications specified in section 1861(11)(1) of the Act and the requirements in 42 CFR 484.	485.705(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-4	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: An administrator is a person who has a bachelor's degree and has experience or specialized training in the administration of health institutions or agencies; or is qualified and has experience in one of the professional health disciplines.	485.705(c) Standard 485.705(c)(1) Standard 485.705(c)(1)(i) Standard 485.705(c)(1)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-5	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: An occupational therapist must meet the requirements in part 484 of this chapter.	485.705(c)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-A-6	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: An occupational therapy assistant must meet the requirements in 42 CFR 484 of this chapter.	485.705(c)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-7	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A physical therapist must meet the requirements in 42 CFR 484 of this chapter.	485.705(c)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-8	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A physical therapist assistant must meet the requirements in 42 CFR 484 of this chapter.	485.705(c)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-A-9	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A social worker must meet the requirements in 42 CFR 484 of this chapter.	485.705(c)(6) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-10	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A vocational specialist is a person who has a baccalaureate degree and two years' experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment agency, etc.; or at least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or a master's degree in vocational counseling.	485.705(c)(7) Standard 485.705(c)(7)(i) Standard 485.705(c)(7)(ii) Standard 485.705(c)(7)(iii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-A-11	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A nurse practitioner is a person who: 1) must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and 2) be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or	485.705(c)(8) Standard 485.705(c)(8)(i) Standard 485.705(c)(8)(ii) Standard 485.705(c)(8)(iii) Standard 485.705(c)(8)(iv)	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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>3) be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; or</p> <p>4) be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in items 1 and 2 above; or</p> <p>5) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in items 1 and 2 above.</p>	<p>Standard</p> <p>485.705(c)(8)(v)</p> <p>Standard</p>		
15-A-12	<p>Suppose no State licensing laws or State certification or registration requirements exist for the profession. In that case, the following requirement must be met: A clinical nurse specialist is a person who must be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law; have a master's degree in a defined clinical area of nursing from an accredited educational institution; and be certified as a clinical nurse specialist by the American Nurses Credentialing Center.</p>	<p>485.705(c)(9)</p> <p>Standard</p> <p>485.705(c)(9)(i)</p> <p>Standard</p> <p>485.705(c)(9)(ii)</p> <p>Standard</p> <p>485.705(c)(9)(iii)</p> <p>Standard</p>	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-A-13	If no State licensing laws or State certification or registration requirements exist for the profession, the following requirement must be met: A physician assistant is a person who has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and is licensed by the State to practice as a physician assistant.	485.705(c)(10) Standard 485.705(c)(10)(i) Standard 485.705(c)(10)(ii) Standard 485.705(c)(10)(iii) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION B: Compliance with Federal, State, and Local Laws				
15-B-1	The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.	485.707 Condition	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-B-2	In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.	485.707(a) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-B-3	Staff of the organization are licensed or registered in accordance with applicable laws.	485.707(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION C: Administrative Management				
15-C-1	The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator and establishes administrative policies.	485.709 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-C-2	There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State Agency and QUAD A. In the case of corporations, the names of the corporate officers are made known.	485.709(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-C-3	The governing body appoints a qualified full-time administrator.	485.709(b) Standard 485.709(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-C-4	The governing body delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies.	485.709(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-C-5	The governing body defines clearly the administrator's responsibilities for procurement and direction of personnel.	485.709(b)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-C-6	The governing body designates a competent individual to act during temporary absence of the administrator.	485.709(b)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-C-7	Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.	485.709(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-C-8	Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel and revised as necessary based upon this evaluation.	485.709(d)	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION D: Plan of Care and Physician Involvement				
15-D-1	For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.	485.711 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-D-2	The patient's significant past history is obtained by the organization before or at the time of initiation of treatment.	485.711(a) Standard 485.711(a)(1) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-3	Current medical findings, if any, are obtained by the organization before or at the time of initiation of treatment.	485.711(a)(2) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-4	Diagnosis(es), if established, are obtained by the organization before or at the time of initiation of treatment.	485.711(a)(3) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-5	Physician's orders, if any, are obtained by the organization before or at the time of initiation of treatment.	485.711(a)(4) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-D-6	Rehabilitation goals, if determined, are obtained by the organization before or at the time of initiation of treatment.	485.711(a)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-7	Contraindications, if any, are obtained by the organization before or at the time of initiation of treatment.	485.711(a)(6) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-8	The extent to which the patient is aware of the diagnosis(es) and prognosis is obtained by the organization before or at the time of initiation of treatment.	485.711(a)(7) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-9	If appropriate, the summary of treatment furnished, and results achieved during previous periods of rehabilitation services or institutionalization is obtained by the organization before or at the time of initiation of treatment.	485.711(a)(8) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-D-10	For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.	485.711(b) Standard 485.711(b)(1) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-11	The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the type, amount, frequency, and duration.	485.711(b)(2) Standard 485.711(b)(2)(i) Standard 485.711(b)(2)(ii) Standard 485.711(b)(2)(iii) Standard 485.711(b)(2)(iv) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-12	The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken.	485.711(b)(3) Standard	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-D-13	Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.	485.711(b)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-D-14	Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.	485.711(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
5-D-14	Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.	485.711(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
SUB-SECTION E: PHYSICAL THERAPY SERVICES				
15-E-1	If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.	485.713 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-2	The organization is considered to have an adequate outpatient physical therapy program if it can provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity.	485.713(a) Standard 485.713(a)(1) Standard 485.713(a)(1)(i) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-3	The organization is considered to have an adequate outpatient physical therapy program if it can conduct patient evaluations.	485.713(a)(1)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-E-4	The organization is considered to have an adequate outpatient physical therapy program if it can administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.	485.713(a)(1)(iii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-5	A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.	485.713(a)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-6	If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.	485.713(a)(2)(i) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-7	When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every thirty (30) days.	485.713(a)(2)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-E-8	The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.	485.713(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-9	Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.	485.713(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-E-10	If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.	485.713(d) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
SUB-SECTION F: Occupational Therapy Services				
15-F-1	If the organization offers occupational therapy services, it provides an adequate program of occupational therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-2	The organization is considered to have an adequate outpatient occupational therapy program if it can provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity.		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-3	The organization is considered to have an adequate outpatient occupational therapy program if it can conduct patient evaluations.		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-4	The organization is considered to have an adequate outpatient occupational therapy program if it can administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.		Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-F-5	A qualified occupational therapist is present or readily available to offer supervision when an occupational therapist assistant furnishes services.		<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-6	If a qualified occupational therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.		<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-7	When a occupational therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified occupational therapist who makes an onsite supervisory visit at least once every thirty (30) days.		<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-8	The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.		<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</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
15-F-9	Occupational therapy services are provided by, or under the supervision of, a qualified occupational therapist. The number of qualified occupational therapists and qualified occupational therapist assistants is adequate for the volume and diversity of occupational therapy services offered. A qualified occupational therapist is on the premises or readily available during the operating hours of the organization.		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-F-10	If personnel are available to assist qualified occupational therapists by performing services incident to occupational therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified occupational therapists who retain responsibility for the treatment prescribed by the attending physician.		Interpretive Guidance: Evaluating Compliance:	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION G: Speech Pathology Services				
15-G-1	If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.	485.715 Condition	Interpretive Guidance: Evaluating Compliance: CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E	<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
15-G-2	The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.	485.715(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-G-3	The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.	485.715(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-G-4	Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.	485.715(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
SUB-SECTION H: Rehabilitation Program				
15-H-1	This condition and standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to which the agency furnishes services. The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients. The rehabilitation agency provides physical therapy and speech-language pathology services to all of its patients who need them.	485.717 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-H-2	The agency's therapy services are furnished by qualified individuals as direct services and/or services provided under contract.	485.717(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-H-3	If services are provided under contract, the contract must specify the term of the contract, the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.	485.717(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
SUB-SECTION I: Arrangements For Services To Be Performed By Other Than Salaried Organization Personnel				
15-I-1	Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.	485.719(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-I-2	If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.	485.719(b) Standard 485.719(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-I-3	The contract specifies the term of the contract and the manner of termination or renewal.	485.719(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-I-4	The contract requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel.	485.719(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-I-5	The contract provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that only the provider may bill the beneficiary for covered services furnished under arrangements; and receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.	485.719(b)(3) Standard 485.719(b)(3)(i) Standard 485.719(b)(3)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION J: Clinical Records				
15-J-1	The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.	485.721 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-J-2	The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.	485.721(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-3	The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. (Includes stem statement)	485.721(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-4	All clinical records contain documented evidence of the assessment of the needs of the patient, of an appropriate plan of care, and of the care and services furnished.	485.721(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-5	All clinical records contain identification data and consent forms.	485.721(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-J-6	All clinical records contain medical history.	485.721(b)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-7	All clinical records contain report of physical examinations, if any.	485.721(b)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-8	All clinical records contain observations and progress notes.	485.721(b)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-9	All clinical records contain reports of treatments and clinical findings.	485.721(b)(6) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-J-10	All clinical records contain discharge summary including final diagnosis(es) and prognosis.	485.721(b)(7) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-11	Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.	485.721(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-12	Clinical records are retained for at least the period determined by the respective State statute, or the statute of limitations in the State; or	485.721(d) Standard 485.721(d)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-13	In the absence of a State statute, clinical records are retained for at least five years after the date of discharge; or in the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.	485.721.(d)(2) Standard 485.721(d)(2)(i) Standard 485.721(d)(2)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-J-14	Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.	485.721(e) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-J-15	The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).	485.721(f) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION K: Physical Environment				
15-K-1	The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.	485.723 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-2	The facility must comply with all applicable State and local building, fire, and safety codes.	485.723(a) Standard 485.723(a)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-K-3	The facility must ensure that permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.	485.723(a)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-4	The facility must ensure that doorways, passageways and stairwells negotiated by patients are of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs).	485.723(a)(3) Standard 485.723(a)(3)(i) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-5	The facility must ensure that doorways, passageways and stairwells negotiated by patients are free from obstruction at all times.	485.723(a)(3)(ii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-6	The facility must ensure that doorways, passageways and stairwells negotiated by patients are in the case of stairwells, equipped with firmly attached handrails on at least one side.	485.723(a)(3)(iii) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-K-7	The facility must ensure that lights are placed at exits and in corridors used by patients and are supported by an emergency power source.	485.723(a)(4) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-8	The facility must ensure that a fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.	485.723(a)(5) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-9	The facility must ensure that at least two persons are on duty on the premises of the organization whenever a patient is being treated.	485.723(a)(6) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-10	The facility must ensure that no occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.	485.723(a)(7) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-K-11	The organization establishes a written preventive-maintenance program to ensure that the equipment is operative, and is properly calibrated.	485.723(b) Standard 485.723(b)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-12	The organization establishes a written preventive-maintenance program to ensure that the interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.	485.723(b)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-13	The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.	485.723(c) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-14	Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or a combination of both.	485.723(c)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-K-15	Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semi-ambulatory individuals.	485.723(c)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-K-16	Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.	485.723(c)(3) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION L: Infection Control				
15-L-1	The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.	485.725 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-L-2	The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.	485.725(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-L-3	All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.	485.725(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-L-4	The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.	485.725(c) Standard 485.725(c)(1) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-L-5	An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.	485.725(c)(2) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-L-6	The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.	485.725(d) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-L-7	The organization's premises are maintained free from insects and rodents through operation of a pest-control program.	485.725(e) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
SUB-SECTION M: Program Evaluation				
15-M-1	The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.	485.729 Condition	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.
15-M-2	Standard: Clinical-record review. A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.	485.729(a) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</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
15-M-3	Standard: Annual statistical evaluation. An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.	485.729(b) Standard	<p>Interpretive Guidance:</p> <p>Evaluating Compliance:</p> <p>CMS standards Interpretive Guidance can be found at: SOM(cms.gov)Appendix E</p>	<input type="checkbox"/> Compliant <input type="checkbox"/> Deficient Enter observations of non-compliance, comments or notes here.

GLOSSARY

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

Clinical Personnel refers to all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization. Including, but not limited to, physical therapist, physical therapist assistant, occupational therapist, occupational therapist assistant, speech-language pathologist, social worker, etc.

The **Clinic Administrator** is responsible for the internal operation of the facility 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)]*

Clinic -

- A facility 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]

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]

Organization-

A clinic, rehabilitation agency, or public health agency.

[485.703 Condition]

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]

GLOSSARY (cont.)

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]

Supervision -

- Authoritative procedural guidance that is for the accomplishment of a function or activity and that:
- Includes initial direction and periodic observation of the actual performance of the function or activity; and
- Is furnished by a qualified person—
- Whose sphere of competence encompasses the particular function or activity; and
- Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in §485.705.

[485.703 Condition]

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

***** 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 antiseptis (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:

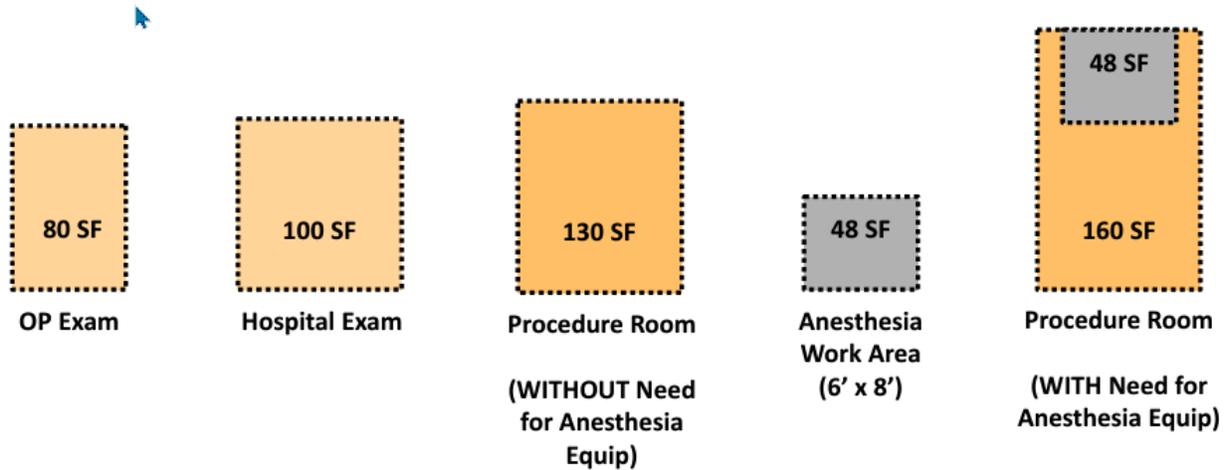
- Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
- Provides at least physical therapy or speech-language pathology services.

[485.703 Condition]

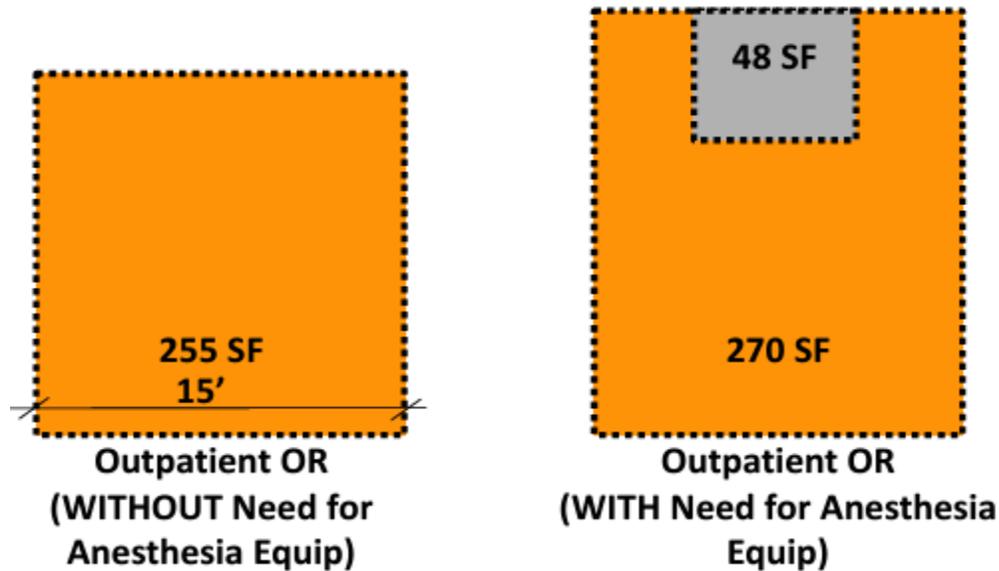
**** Room Classifications:

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	Invasive procedures* Any procedure during which the patient will require physiological monitoring and is anticipated to require active life support	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
SURGERY AND CRITICAL CARE							
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
DIAGNOSTIC AND TREATMENT							
Gastrointestinal endoscopy procedure room	Positive	2	6	N/R	No	20-60	68-73/20-23

SPECIAL THANKS & RECOGNITION

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