

MEDICARE OUTPATIENT PHYSICAL THERAPY (OPT)

ACCREDITATION STANDARDS MANUAL

Version, 4.1 Effective February 2, 2026

SURVEY INSTRUCTIONS

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

STANDARDS STRUCTURE

Standards found in this book are organized by grouping relevant standards together. These groupings are comprised of "Sections," "Sub-sections," and then individual standard numbers. Each main "Section" is identified by a numerical value, "Sub-sections" have been assigned an alphabetical value, and the individual standards under the subsection have also been numbered. Based on this format, each standard has been assigned a unique identifier to include all three elements to indicate its location.

For example: The standard which states, "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.

The standards are organized into a logical hierarchy for ease of use:

- **Sections** are numbered (e.g., 1, 2, 3).
- **Sub-sections** are assigned a letter (e.g., A, B, C).
- **Individual Standards** are numbered under each sub-section (e.g., 1, 2, 3).

This structure creates a unique identifier for each standard: [**Section**]-[**Sub-section**]-[**Standard #**].

Example: The standard, *"Each operating room is properly cleaned, maintained and free of litter and clutter,"* is the fourth standard in Section 2, Sub-section C. Its identifier is **2-C-4**.

Please Note:

- Standard numbers are not always sequential. Some numbers are reserved for future use and do not appear in this edition.

  The groupings are designed to cluster related standards, which may facilitate a more efficient survey process.

STANDARDS BOOK LAYOUT

The standards manual layout consists of five (5) columns. The function of each column is as follows:

Standard ID:

This column contains the alphanumerical identifier for each standard.

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 it.

Note: Facilities must comply with all applicable state or national requirements governing the facility, including country and state laws and regulations relating to anesthesia. When standards conflict, **the most stringent requirement applies,** unless mandated by laws or regulations applicable to the facility.

Example: A facility accredited under QUAD A Class A Standards may be permitted to administer local, topical anesthesia, minimal sedation, or nitrous oxide using a standalone system for administration. However, if the facility's state or country has a Class A–equivalent designation that *specifically limits anesthesia to local or topical anesthesia only*, then the facility must follow the state or national requirement. In this case, the facility **may not** administer oral medications to achieve minimal sedation, even if accreditation standards would otherwise allow it.

Standard / Regulatory Reference:

This column contains the text for each standard. It also indicates the corresponding regulatory reference (e.g., CMS, DHA, Florida, etc.), if applicable.

Interpretive Guidance:

This column indicates the interpretive guidance (IG) that correlates with the standard.

INTERPRETIVE GUIDANCE (IG)

Interpretive Guidance (IG) is provided to support the understanding and application of QUAD A standards. IGs are **explanatory tools**, not requirements, and are **not used as scorable elements** during the accreditation process.

Purpose of Interpretive Guidance

Interpretive Guidance is intended to:

- **Clarify the intent** of a standard by explaining the underlying objectives related to patient safety and quality.
- **Offer examples** of acceptable methods, processes, or documentation that a facility *may* use to demonstrate compliance. These examples are illustrative and not mandatory.
- **Promote consistency** among surveyors by identifying common areas of review and evidence-gathering related to the standard.
- **Encourage continuous improvement** as facilities assess their policies and procedures in relation to the goals of the standard.

Use of IGs in the Accreditation Process

Interpretive Guidance supplements the standards but **does not function as an additional layer of requirements**. Accreditation decisions are based solely on a facility's compliance with the published QUAD A standards.

- IG examples are **not scoreable** and cannot be used as the basis for a citation.
- A facility may demonstrate compliance through methods other than those listed in an IG, as long as the approach meets the requirements of the standard.
- Conversely, mirroring an IG example does not guarantee compliance if the underlying standard is not effectively met or implemented.

Survey Application

During the on-site survey:

1. **The Standard Serves as the Benchmark**
   Surveyors evaluate compliance directly against the language of the standard.
2. **The IG Informs the Review Process**
   Surveyors use IGs to guide their inquiry, including selecting relevant questions and identifying appropriate sources of evidence.
   Example: If a standard requires a "qualified circulator," the IG may suggest reviewing credentials or competency assessments. Evidence of qualifications may be demonstrated through personnel files, competency documentation, or other facility-established methods.
3. **Compliance Is Evidence-Based**
   The surveyor determines compliance by assessing whether the evidence provided—regardless of format—meets the requirement described in the standard.

SCORING COMPLIANCE

The QUAD A accreditation program mandates 100% compliance with every standard to achieve and maintain accreditation, without exception. If a surveyor observes a single instance of non-compliance, the standard is scored as “Deficient.” The facility must submit both a Plan of Correction, as well as documented Evidence of Corrections.

Applicable standard(s) will be given a score of deficient.

QUAD A withholds accreditation until the facility submits acceptable Plans of Correction and Evidence of Corrections for all cited deficiencies. However, when a standard refers to "*appropriate*," "*proper*," or "*adequate*", reasonable flexibility and room for consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised.

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SECTION 1: BASIC MANDATES

Standard ID	Standard Language / Regulation	Interpretive Guidance
Sub-section B: Basic Mandates		
1-B-7	Only recognized abbreviations are allowed to be used in the clinical record.	Verify the facility promotes patient safety by using only approved medical abbreviations for consistency in clinical records. The facility may adopt a recognized reference (e.g., MedicineNet, Taber's) or create its own approved list. **Evaluating Compliance**: Review policies for the official list of approved abbreviations (external reference or internal policy) Confirm that abbreviations used in clinical records align with the approved list.
1-B-8	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: 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.	Verify the facility performs annual self-surveys, documents non-compliance, and takes corrective actions to maintain compliance with QUAD A standards. **Evaluating Compliance:** Review documents for evidence that the most recent self-survey includes all required elements Confirm availability of self-surveys from the past three (3) years.
Sub-section E: QUAD A-Mandated Reporting		
1-E-1	Changes in facility ownership must be reported to the QUAD A Central Office within thirty (30) days of the change.	Verify QUAD A records accurately reflect current facility ownership. **Evaluating Compliance:** Interview leadership regarding current ownership Review facility documents to confirm QUAD A records were updated if a change

Standard ID	Standard Language / Regulation	Interpretive Guidance
		in ownership occurred. If there were no changes in ownership, mark as compliant.
1-E-2	Any change in provider staff must be reported to the QUAD A Central Office, in writing, within thirty (30) days of the change, along with the appropriate credentials. **Surgical Programs (ASC, OBS, OBP, PD, OMS, I-DENT, I-SURG):** Surgeons, Proceduralists, and Pain Management Providers must submit medical license, board certification or board eligibility, and delineation of facility privileges. **RHC:** Physicians, Advanced Practice Providers (NP, PA, CNM) and licensed behavior health providers (CP, CSW, MFT, MHC) must submit professional licenses. **Physical Therapy (OPT, I-PT):** SLP, OT, PT, SLPA, OTA, PTA must submit professional licenses. **Polyclinic:** Physicians, Dentist, Advanced Practice Providers (NP, PA, CNM), Physiotherapist, and Physical Therapists must submit must professional licenses.	Verify QUAD A records accurately reflect the licensed providers performing procedures, treatments, or furnishing patient care services in the facility. **Evaluating Compliance:** Review documents and credentialing/personnel files to confirm the list of licensed providers performing surgery, procedures (excluding those solely providing surgical anesthesia services), treatments, or furnishing patient care services. If changes have occurred, confirm timely reporting to QUAD A within 30 days.
1-E-3	Any action affecting the current professional license of any licensed facility 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.	Verify the facility reports to QUAD A any adverse licensure actions (e.g., suspension, probation, revocation, practice restrictions/limitations, etc.) of any professionally licensed staff working in the facility. **Evaluating Compliance:** Review credentialing files for active license status and documentation of adverse actions If present, confirm timely reporting to QUAD A within 30 days Interview staff regarding monitoring procedures and reporting protocols for adverse licensure actions.

SECTION 2: FACILITY LAYOUT & ENVIRONMENT

Standard ID	Standard Language / Regulation	Interpretive Guidance
Sub-section B: Facility Environment		
2-B-19	Smoking is prohibited in the entire facility.	Verify smoking is not allowed within the facility. **Evaluating Compliance:** Review policies for the adoption of a smoking ban Review facility documents to ensure employee handbooks and patient materials reinforce “no smoking” Inspect the facility for posted "No Smoking/Vaping" signs at entrances and key areas Observe for compliance among patients, guests, and staff.
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.	Verify the facility complies with the manufacturer’s instructions for use (IFU) and expiration dates of supplies and devices to ensure safe use in patient care To maintain sterility or integrity, the facility must: Adhere to the manufacturer’s designation for usage (e.g., single-use, reusable) Track the number of re-sterilizations (e.g., LMAs, implant sizers) when a limit is defined Maintain set storage requirements (e.g., temperature ranges) When an item does not come with cleaning and re-sterilization instructions, it must be considered a single-use item with a terminal expiration date. It should not be used after the printed manufacturer’s expiration date, nor should it be re-sterilized after use. Re-processing “expired” supplies is not acceptable unless this process is documented in the manufacturer’s IFU. **Evaluating Compliance:** Interview staff regarding:

Standard ID	Standard Language / Regulation	Interpretive Guidance
		Process for determining the manufacturer's designation for use, any items designated for a limited number of re-sterilizations, and process for checking inventory for temperature ranges and expiration dates Review documents tracking the number of times items are re-sterilized (when limited by the IFU) Inspect storage areas and check for expired supplies, medications, or patient care devices Review facility policy.

SECTION 3: SAFETY

Standard ID	Standard Language / Regulation	Interpretive Guidance
Sub-section D: Medical Hazardous Waste		
3-D-1	All medical hazardous wastes are disposed of in sealed, labeled containers and stored in compliance with federal/national, state, provincial, and local regulations and/or OSHA (Occupational Safety and Health Administration) acceptable containers and separated from general refuse for special collection and handling.	Verify the facility manages medical waste per federal/state or international regulations through: Proper containment (leak-proof biohazard bags/sharps containers) Secure transport/storage protocols Implementing a medical waste plan that addresses: Regular disposal to prevent accumulation Ventilated, pest-proof storage. **Evaluating Compliance:** Review policies to confirm the waste management plan includes: Containment standards (double-bagging if contaminated) Storage/transport requirements Interview staff regarding waste handling procedures Inspect waste disposal containers, procedures, and storage areas for Proper bag/container use (no overfilling) Labeled, puncture-resistant sharps containers Ventilated storage areas.
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.	Verify that the facility maintains safe sharps handling practices to prevent injuries and bloodborne pathogen exposure, in compliance with applicable occupational health, infection prevention, and product safety regulations — including U.S. standards (NIOSH, OSHA, FDA) or equivalent international or national standards (e.g., WHO, ISO, EU Directive 2010/32/EU). Requirements for sharps container design, functionality, and maintenance include: Puncture-resistant, leak-proof, and FDA-cleared Secure closures to minimize exposure Proper labeling (biohazard/warning symbols) Mounted securely or on wheeled bases (if floor-standing) Positioned near point of use and within horizontal reach (52–56 inches height

Standard ID	Standard Language / Regulation	Interpretive Guidance
		recommended) Away from obstructed areas (e.g., under sinks) Replaced at ¾ capacity If reusable, containers must be FDA-approved, marked for reuse, and effectively disinfected. **<u>Evaluating Compliance:</u>** Review policies for alignment with OSHA 1910.1030 (Bloodborne Pathogens) and FDA standards or equivalent local/international regulation. Review documents to ensure any reusable containers meet FDA/DOT, or equivalent local/international regulation, reuse criteria Interview staff regarding one-handed sharps disposal and sharps container emptying practices Observe sharps containers in use to confirm: Fill level ≤ ¾ capacity without protruding sharps Proper mounting or stability Compliance with placement/accessibility guidelines.

SECTION 5: IN CASE OF EMERGENCY

Standard ID	Standard Language / Regulation	Interpretive Guidance
Sub-section D: Emergency Preparedness Plan		
5-D-1	The facility must comply with all applicable Federal, State, and local emergency preparedness requirements. The facility must establish and maintain an emergency preparedness program that meets the requirements of this section. §485.727Condition	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-2	Emergency plan: The facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every two (2) years. §485.727(a) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-4	The plan must include strategies for addressing emergency events identified by the risk assessment. §485.727 (a)(2) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-5	The plan must address patient population, including, but not limited to, the type of services the facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. §485.727(a)(3) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-6	The plan must address the location and use of alarm systems and signals; and methods of containing fire.	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
	§485.727(a)(4) Standard	
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)(4) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-8	The plan must be developed and maintained with assistance from fire, safety, and other appropriate experts. §485.727(a)(6) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-9	Policies and procedures: The facility 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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-11	At a minimum, the policies and procedures must address safe evacuation from the facility. §485.727(b)(1) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-12	Safe evacuation from the facility must include consideration of the care and treatment needs of evacuees. §485.727(b)(1) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-13	Safe evacuation from the facility must include staff responsibilities. §485.727(b)(1) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
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 facility. §485.727(b)(2) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-21	Communication plan: The facility 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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-22	The communication plan must include names and contact information for Staff, Entities providing services under arrangement, Patients' physicians, Volunteers, and other facilities 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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-24	The communication plan must include primary and alternate means for communicating with facility 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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-25	The communication plan must include a method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health care providers to maintain the continuity of care. §485.727(c)(4) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-28	The communication plan must include a means of providing information about the facility'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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-29	Training and testing: The facility 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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-31	The training program must provide emergency preparedness training at least every two (2) years. §485.727(d)(1)(ii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-32	The training program must maintain documentation of all emergency preparedness training. §485.727(d)(1)(iii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-33	The training program must demonstrate staff knowledge of emergency procedures. §485.727(d)(1)(iv) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-34	If the emergency preparedness policies and procedures are significantly updated, the facility must conduct training on the updated policies and procedures. §485.727(d)(1)(v) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-35	The facility must conduct exercises to test the emergency plan at least annually. §485.727(d)(2) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-36	The facility must participate in a full-scale exercise that is community-based every two (2) years; or When a community based exercise is not accessible, conduct a facility-based functional exercise every two 2) years; or If the facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the facility is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
	§485.727(d)(2)(i) Standard §485.727(d)(2)(i)(A) Standard §485.727(d)(2)(i)(B) Standard	
5-D-37	The facility 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: A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or B) A mock disaster drill; or 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. §485.727(d)(2)(ii) Standard §485.727(d)(2)(ii)(A) Standard §485.727(d)(2)(ii)(B) Standard §485.727(d)(2)(ii)(C) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-38	The facility must analyze the facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the facility's emergency plan, as needed. §485.727(d)(2)(iii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
Sub-section E: Emergency Preparedness Plan - Integrated Healthcare Systems		
5-E-1	If a facility 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 facility may choose to participate in the healthcare system's coordinated emergency preparedness program. §485.727(e) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-E-3	If elected, the unified and integrated emergency preparedness program must be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. §485.727(e)(2) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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, and 5-D-7. §485.727(e)(4) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
Sub-section F: Disaster Preparedness Plan		
5-F-1	There is a written protocol for a disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the facility.	Verify the facility's readiness to respond to disasters and emergencies, including: A comprehensive preparedness plan Biennial review/testing Staff competency Key Requirements: Emergency response procedures Staff roles/responsibilities Patient care continuity Resource management. **Evaluating Compliance:** Review the emergency preparedness plan for: Required elements Contact protocols Emergency procedures Review documentation for evidence of biennial review/updates and plan testing Interview staff regarding emergency responses/roles and plan accessibility Review personnel records for evidence of training (initial, annual, updates).

SECTION 7: INFECTION PREVENTION & CONTROL

Standard ID	Standard Language / Regulatory Reference	Interpretive Guidance
Sub-section B: Hand Hygiene		
7-B-1	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. 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.	Verify the facility minimizes infection risk through rigorous hand hygiene protocols that align with CDC/WHO guidelines, including: Surgical hand antisepsis Routine hand hygiene (HH) audits Maintaining accessible HH supplies. **Evaluating Compliance:** Review policies for alignment with adopted national guidelines (e.g., CDC, WHO) Confirm HH policies define audit frequency, methods, and QAPI integration Review documentation of HH audit records for: Regular, unannounced observations Compliance with "WHO Five Moments" (e.g., before patient contact, after environmental contact) Data analysis, feedback, and documented corrective actions HH audits results integration into the facility's QAPI program Interview staff regarding indications for HH and surgical scrub protocols (e.g., brushless technique, duration) Observe practices for adherence during patient care and procedures Inspect facility to ensure alcohol-based hand rub, surgical scrub supplies, and sinks are: Readily accessible in semi-restricted/restricted areas (not expired) Separate from instrument cleaning sinks.
Sub-section C: Instrument Processing		
7-C-1	The facility has a written protocol for the reprocessing of all surgical instruments and disinfection of all equipment used in patient care consistent with the manufacturer's instructions for use.	Verify the facility minimizes infection risk by ensuring all reusable instruments and equipment are reprocessed or disinfected according to manufacturer instructions for use (IFU) and nationally recognized guidelines. This applies to all

Standard ID	Standard Language / Regulatory Reference	Interpretive Guidance
		equipment used in patient care, including point-of-care devices. Contracted reprocessing services must be rigorously monitored through the facility's quality improvement program. **<u>Evaluating Compliance:</u>** Review policies for: Alignment with recognized guidelines (e.g., CDC, AORN, AAMI, WHO) Directive for strict adherence to manufacturer's IFU for all equipment HLD/sterilization procedures and recordkeeping criteria Interview staff regarding ophthalmic instrument reprocessing to prevent TASS and endophthalmitis: Cleaning intraocular instruments in a designated area, separate from general surgical instruments Importance of rinsing/flushing phaco handpieces and cannulas (single-use preferred) Observe staff to ensure: Cleaning/reprocessing occur in between patients use or when contaminated Manufacturer's IFU are strictly followed for high-level disinfection or terminal sterilization Cleaning agents (e.g., enzymatic) and methods (e.g., ultrasonic cleaning) align with IFU Thorough rinsing, flushing, drying occur before disinfection/sterilization Review personnel records for validation of competency (initial, per policy, updates) If the facility uses contracted services for reprocessing: Confirm written contract holds vendor accountable to meet all applicable standards (e.g., ANSI/AAMI ST79) Confirm annual contract review is part of the facility's QAPI program, with a defined process for validating the vendor's compliance, staff competence, and quality outcomes.

SECTION 11: PERSONNEL

Standard ID	Standard Language / Regulation	Interpretive Guidance
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 Assistants · SLP - Speech Language Pathologist.	Verify all practitioners providing services in the clinic are qualified. **Evaluating Compliance:** Interview staff regarding the services offered by the clinic and the provider-type scheduled Review personnel files for evidence of: Primary source verification (initially, periodically) Job description.`
Sub-section I: Personnel Training		
11-I-1	Each personnel record has evidence of annual hazard safety training.	Verify the personnel file includes documentation that annual hazard safety training is administered, to keep staff knowledge of safety protocols current and ensure compliance with federal regulations. Staff must understand the hazards they are likely to encounter and how to identify each one. Control training ensures that they know what to do when encountering biological, chemical, physical, safety, or psychosocial hazards Online training courses using a learning management system are acceptable when the content is reviewed/approved by the facility annually. However, the facility must provide additional training regarding action to be taken in the event of exposure (specific to their facility). Non-specific, general online training is not acceptable. **Evaluating Compliance:** Review personnel files for evidence of annual hazard safety training for all staff Confirm the content is facility specific and covers action plans when hazards are encountered.

11-I-2	Each personnel record has evidence of annual blood borne pathogen training.	Verify the personnel file includes documentation that annual blood borne pathogen (BBP) training is administered to staff with a reasonable risk of exposure to blood or bodily fluids, to minimize exposure risk and ensure compliance with federal regulations. BBP training ensures that clinical staff can identify the risks of exposure, prevent exposure by taking proper precautions, and take effective action in the event of exposure Online training courses are acceptable when the content is reviewed/approved by the facility annually. However, the facility must provide additional training regarding action to be taken in the event of exposure (specific to their facility). Non-specific, general online training is not acceptable. **Evaluating Compliance:** Review personnel files for evidence of annual blood borne pathogen training for all clinical staff Confirm the content is facility specific and covers action plans for exposures.
11-I-3	Each personnel record has evidence of annual standard precaution training.	Verify the personnel file includes documentation that annual standard precaution training is administered to all clinical staff to prevent the transmission of infectious diseases in healthcare settings and ensure compliance with federal/national regulations. Online training courses are acceptable when the content is reviewed/approved by the facility annually. **Evaluating Compliance:** Review personnel files for evidence of annual standard precaution training for all clinical staff.
11-I-13	Where staff cannot demonstrate competency, training, or experience in the safe operation of equipment, the facility provides and documents training or arranges training through an external provider.	Verify staff receive thorough instruction on the effective use of facility equipment that is specific to their position. This allows staff to correctly operate complex medical devices, preventing misuse, malfunction, or harm to patients or themselves. Whether provided by the facility or an external representative, training content must align with the equipment's instructions for use. Competency should be accessed initially and periodically. **Evaluating Compliance:** Interview staff regarding:

		How the facility assesses competency to run specialized equipment (e.g., self-assessment, qualified peer observation) What equipment requires training by an external expert (e.g., robotic equipment, lasers) Review personnel files for evidence of competency for job-specific equipment (initial, per policy).

SECTION 15: REHABILITATION AGENCY / OUTPATIENT PHYSICAL THERAPY (RA/OPT)

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
	§485.705(c)(1) Standard §485.705(c)(1)(i) Standard §485.705(c)(1)(ii) Standard	
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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 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 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 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. §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) Standard §485.705(c)(8)(v) Standard	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
15-A-12	If no State licensing laws or State certification or registration requirements exist for the profession, 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. §485.705(c)(9) Standard §485.705(c)(9)(i) Standard §485.705(c)(9)(ii) Standard §485.705(c)(9)(iii) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
15-B-3	Staff of the organization are licensed or registered in accordance with applicable laws. §485.707(b) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
15-C-3	The governing body appoints a qualified full-time administrator. §485.709(b) Standard §485.709(b)(1) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT
15-C-5	The governing body defines clearly the administrator's responsibilities for procurement and direction of personnel. §485.709(b)(3) Standard	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
15-C-6	The governing body designates a competent individual to act during temporary absence of the administrator. §485.709(b)(4) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
15-D-14	The rehabilitation agency must establish procedures to be followed by personnel in an emergency, which cover **immediate** care of the patient, persons to be notified, and reports to be prepared. §485.711(c) Standard	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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.	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
	§485.713(a)(2)(i) Standard	
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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.	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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.	SOM Appendix E - OPT
15-F-3	The organization is considered to have an adequate outpatient occupational therapy program if it can conduct patient evaluations.	SOM Appendix E - OPT
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.	SOM Appendix E - OPT
15-F-5	A qualified occupational therapist is present or readily available to offer supervision when an occupational therapist assistant furnishes services.	SOM Appendix E - OPT
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.	SOM Appendix E - OPT
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.	SOM Appendix E - OPT
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.	SOM Appendix E - OPT
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.	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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.	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
	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	
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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 Condition	SOM Appendix E - OPT
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(a) Standard	SOM Appendix E - OPT
15-I-3	The contract specifies the term of the contract and the manner of termination or renewal. §485.719(b) Standard §485.719(b)(1) Standard	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
15-J-5	All clinical records contain identification data and consent forms. §485.721(b)(2) Standard	SOM Appendix E - OPT
15-J-6	All clinical records contain medical history. §485.721(b)(3) Standard	SOM Appendix E - OPT
15-J-7	All clinical records contain report of physical examinations, if any. §485.721(b)(4) Standard	SOM Appendix E - OPT
15-J-8	All clinical records contain observations and progress notes. §485.721(b)(5) Standard	SOM Appendix E - OPT
15-J-9	All clinical records contain reports of treatments and clinical findings. §485.721(b)(6) Standard	SOM Appendix E - OPT
15-J-10	All clinical records contain discharge summary including final diagnosis(es) and prognosis. §485.721(b)(7) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
15-K-13	The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public. §485.723(c) Standard	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
Sub-section L: Infection Prevention and Control		
15-L-1	The organization that provides outpatient physical therapy services establishes an infection prevention and 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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
	§485.725(c)(1) Standard	
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT
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	SOM Appendix E - OPT

Standard ID	Standard Language / Regulation	Interpretive Guidance
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	SOM Appendix E - OPT

GENERAL GLOSSARY FOR ALL PROGRAMS

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 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 antisepsis (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. ***[§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.

** **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.

*** **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]***

* **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.

Equipment: The term "equipment" refers to the requirement that the specific item named must meet current performance standards according to the manufacturer's guidelines.

***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]***

Frequent: Occurring or done on many occasions or in quick succession; happening often.

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.

Instrument: Any tool, device, or apparatus used in medicine for the purpose of diagnosing, preventing, treating, or alleviating illness or injury. It encompasses a wide range of items, from simple tools like stethoscopes to complex machines like MRI scanners. Medical instruments can be used to examine the body, record physiological processes, administer treatments, or perform surgical procedures.

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)*

Major Blood Vessels: A group of critical arteries and veins including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, and any intra-cerebral artery or vein.

**** 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 patient's 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.

Office Surgery: Refers to invasive procedures performed under anesthesia or sedation in an outpatient provider's office or other non-hospital setting.

Oral Maxillofacial Surgeon (OMF): 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.

Pediatric Patients: In Florida, pediatric patients are defined as those who are 13 years of age or under. For all other QUAD A facilities, pediatric patients are defined by facility policy and procedure, which must consider age, BMI or weight, special needs, risk categories, surgery, facility equipment, and capability, unless otherwise defined by the state.

**** 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/

Percutaneous endovascular intervention: A procedure performed without an open direct visualization of the target vessel requires only needle puncture of an artery or vein, followed by insertion of catheters, wires, or similar devices, which are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location various maneuvers to address the diseased area may be performed which include, but are not limited to, injection of contrast for imaging, treatment of vessels with angioplasty, atherectomy, covered or uncovered stenting, intentionally occluding vessels or organs (embolization), and delivering medications, radiation, or other energy such as laser, radiofrequency, or cryo.

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.

Polyclinic: An outpatient clinic that is a free-standing medical facility, designed to receive and undergo patients to necessary medical examinations and treatments, encompassing a minimum of two (2) different specialties which may include diagnostics, dental and Traditional Complimentary Alternative Medicine (TCAM) services, to patients that do not stay overnight.

Proceduralist: A licensed physician, usually a specialist or subspecialist, trained and qualified to perform diagnostic or therapeutic procedures. A licensed trained CRNA, NP 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.).

Professional Appearance: relates to both the appearance of people and the appearance of the facility.

A healthcare provider's personal appearance must project professionalism and competence to engender trust in patients. A provider also conveys professionalism in how they communicate, how they express courtesy, body language, and what they wear. E.g., as professional healthcare providers, facility staff should appear clean and well dressed. The facility should appear clean, neat, and furnished for patients, staff, and visitor comfort.

Examples:

- As professional healthcare providers, facility staff should appear clean and well dressed. When interacting with patients and patient families, the facility staff should be friendly, knowledgeable, and culturally sensitive.
- The facility should appear clean, neat, and furnished for patients, staff, and visitor comfort

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.

Promptly: Without delay; immediately

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.

Random Sample: An unbiased representation of a group.

Example:

- For PSDR reporting, QUAD A recommends entering the first case as performed each month to obtain a random sample of cases entered into the quarterly reporting system. If no cases are performed in a given month, any other case can be selected at random from the period.

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]

Routine: A habit or sequence that does not vary; things that must be done on a regular basis.

*** **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]**

Significant: Having or likely to have influence or effect; or of a noticeable or measurably large amount.

Examples:

- As determined by both the surgeon/proceduralist and anesthesia provider, the patient and procedural risk must be assessed pre-operatively. If this risk level is above a

facility's defined threshold, then the patient should be referred to an alternative, safer facility for the operation.

- Current safe levels of ethylene oxide or glutaraldehyde exposure must be identified. Badge testing to maintain exposure under the threshold must be performed and monitored.

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.

** **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).

Sufficient/sufficiently means enough to meet the needs of a situation or a proposed end. E.g., A hallway would be sufficiently wide if healthcare providers can wheel a patient in a gurney and all necessary medical equipment with the gurney in case of emergency.

Example:

- A hallway would be sufficiently wide if healthcare providers can wheel a patient in a gurney and all necessary medical equipment with the gurney in case of emergency. (3-F-4)

Supernatant fat: The fat that rises to the top and separates from other fluids or tissues during processes such as liposuction. In the context of cosmetic surgery, it is important to manage the amount of supernatant fat removed to ensure patient safety and compliance with medical regulations.

Surgeon: A licensed 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.

Track and Trend: Track, as in keep track of, is to follow specific record(s) or specific types of information over a defined period. To trend means to follow the general movement over time of a statistically detectable change. Tracking and trending are commonly used together which means a trail of data is followed to identify changes in outcomes over time.

Examples**:**

- Each facility's written QI program must follow identified records or types of information over a lengthy period of time to identify changes. Based on those changes, or lack thereof, the facility must evaluate and resolve problems, then adjust the identified records or types of information as appropriate.
- Each facility's risk management program must perform an annual risk assessment. This assessment should cover risks as related to patients and staff by medication management, fall hazards, infection control, equipment safety, patient risk resulting from long term conditions, and nutrition if any food or beverage services are available to patients. The trends of these risks across the years should be noted.
- Adverse events are to be noted and discussed during periodic peer review meetings.
- All adverse events should be looked at cumulatively.

GENERAL REFERENCES BY STANDARD ALL PROGRAMS

Note – This reference list contains references for standards across all QUAD A programs.

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