

GENERAL GLOSSARY

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

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

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

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

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

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

Ambulatory Health Care vs Business Occupancy https://cdn.ymaws.com/nehes.site-ym.com/resource/resmgr/presentations/2018/doc_presentation_cable081718.pdf

*** Ambulatory surgical center (ASC): Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2. [42 CFR 416.2]

Ambulatory Services: for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered



ancillary services that are furnished in an ASC in connection with covered surgical procedures. **[42 CFR 416.2]**

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

- ** **Antisepsis:** The application of an antimicrobial chemical to the skin or mucous membrane to reduce the microbial population.
- ** **Antiseptic:** An agent used for 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. [CMS §485.705(c)(1) and §485.709(b)]
- *** Clinical Personnel: The entire clinical team providing services in the facility, including, but not limited to, all physicians/surgeons/proceduralists, anesthesia providers, nurses, scrub techs, physician assistants, physical/occupational/speech therapists and assistants, social workers, clinical psychologists, marriage and family therapists, mental health counselors, medical assistants, etc. Employment status (owner, employee, contractor, contracted, indirect employee, prn staff, etc.) is not a factor in defining who is included as Clinical Personnel.
- *** Covered ancillary services: items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. [42 CFR 416.2]
- *** Covered surgical procedures: surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. [42 CFR 416.2]
- ** **Contact Time:** "Wet time," also known as "contact time" or "dwell time," is the amount of time a disinfectant or antiseptic solution must remain wet and in direct contact with a target microorganism or on a surface to be effective. This time can range from 15 seconds to 10 minutes, which is the maximum time allowed by the US Environmental Protection Agency (EPA). The contact time is established by the product manufacturer.



** **Contamination:** The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.

Contemporaneously: Originating, existing, or happening during the same period of time.

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

Continuous: Prolonged without interruption at any time.

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

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

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

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

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

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

- ***Direct Services means services provided by the clinic's staff. [42 CFR 491.2]
- ** **Disinfectant:** A chemical agent used to kill viruses and bacteria on surfaces. It must be an EPA-registered disinfectant with bactericidal, tuberculocidal, and virucidal properties with specific claims and instructions for HIV and HBV.
- ** **EPA-Registered:** An EPA registration number signifies that a disinfectant and its claims have been reviewed and approved by the United States Environmental Protection Agency.
- ***Extension Location: A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the



extension location to independently meet the conditions of participation as a rehabilitation agency. [485.703 Condition]

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

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

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

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

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

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

- ** Healthcare-Associated Infection (HAI): An infection acquired by patients while they are receiving medical care, with confirmation of diagnosis by clinical or laboratory evidence. Infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the healthcare setting.
- ** Immediate Use Steam Sterilization (IUSS): An abbreviated process of steam sterilization of patient care instruments (or devices) for immediate use.

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



unencumbered by conflicting duties or responsibilities, 3) responding without delay when notified.

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

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

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

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

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

Examples:

- On any day that controlled substances are administered, the controlled substance inventory and control record (log/register) must be updated as appropriate to reflect controlled substances administered, received, wasted, and currently stored by two licensed healthcare professionals. (6-D-2)
- A written record (log/register) of all operative cases is maintained by the facility. (8-L-1)
- ** **Mechanical (Physical) Indicator:** Monitors (embedded into the sterilization equipment) that register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence the sterilization system has met the set parameters (or has not, and there is a need for corrective action).

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

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



- * **Minimal Sedation**: A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.
- * Moderate Sedation/Analgesia ("Conscious Sedation" or "Procedural Sedation): A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- * Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation; rather, it describes "a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure." Indications for monitored anesthesia care include "the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic).

National Fire Protection Association (NFPA) Business Occupancies, 2021 https://www.nfpa.org/news-blogs-and-articles/blogs/2021/05/07/occupancy-classifications-and-model-codes

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

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

- *** **Nurse Practitioner (NP)**: A person who is currently licensed to practice in the State and meets the applicable State requirements governing the qualifications of nurse practitioners. And meets at least one (1) of the following conditions:
 - 1) Is certified as a practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice or
 - 2) Has satisfactorily completed a formal one (1) academic year educational program that:



- i. Prepares registered nurses to perform an expanded role.
- ii. That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.
- iii. Awards a degree, diploma, or certificate to persons who successfully complete the program.
- 3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role) that does not meet the requirements identified above in paragraph 2, and the Nurse Practitioner has been performing an expanded role in the delivery of care for a total of 12 months during the 18-month period immediately preceding the effective date of the subpart.

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

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

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

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

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

- 1) Four (4) years of dental school.
- 2) Two (2) additional years of residency training in dentistry for infants, children, teens, and children with special needs.
- 3) A minimum of 24 months in an advanced education program accredited by the Commission on Dental Accreditation of the American Dental Association. Such programs



- "must be designed to provide special knowledge and skills beyond the Doctor of Dental Surgery (DDS) or Doctor of Medicine in Dentistry (DMD) training.
- 4) A curriculum of an advanced program provides the dentist with the necessary didactic background and clinical experiences to provide comprehensive primary oral health care and the services of a specialist.
- ** Peel Pouch: A sterilization pouch (or peel pack) is a disposable package validated for use in a sterilizer to allow penetration of the sterilant to the items placed inside. After sterilization, peel pouches maintain the sterility of the processed item(s) during storage and until needed for use. Pouches are designated as Class II medical devices and may be self-sealing or heat-sealing. "Double pouching" should only be performed if validated for the specific type of pouch and when the manufacturer's instructions for use provide the method of packaging and the sterilization parameters.

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

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

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

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

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

- ** Personal Protective Equipment (PPE): Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury and minimize exposure to hazards.
- *** **Physician**: Providers who medically diagnose patients, prescribe and manage medication, and supervise other medical staff A licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO) legally authorized to practice medicine or surgery in the State in which the function is performed; and a Doctor of Dental Surgery (DDS) or Doctor of Dental Medicine (DMD) who is



legally authorized to practice dentistry by the State in which he/she performs such function and who is acting within the scope of his/her license and a Doctor of Podiatric Medicine

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

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

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

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

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



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

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

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

Rehabilitation agency -

An agency that:

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

[485.703 Condition]

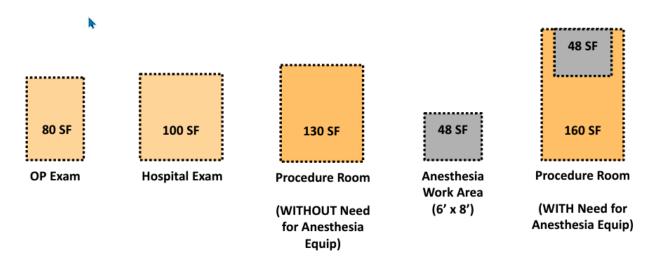


**** Room Classifications:

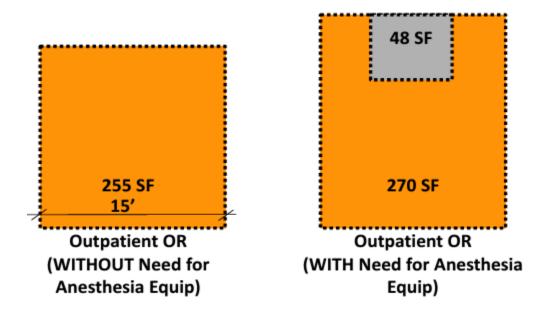
Room Type	Use	Environmental Controls					
		Location	Ventilation (excerpted from ASHRAE 170)	Surfaces			
Exam Room or Treatment Room	Patient care that may require high-level disinfected or sterile instruments but does not require the environmental controls of a procedure room	Accessed from an unrestricted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



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



2018 FGI Guidelines for Minimum Room Sizes: Operating Rooms



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



- *** Rural health clinic: a clinic located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases and meets all other requirements of this subpart. [42 CFR 491.2]
- *** **Secretary:** The Secretary of Health and Human Services, or any official to whom he/she has delegated the pertinent authority.
- *** **Shortage area:** a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act). **[42 CFR 491.2]**

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

- *** Direct Services: services provided by the clinic's staff. [42 CFR 491.2]
- ** **Sterile:** The state of being free from all living microorganisms. In practice, it is usually described as a probability function (e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000).
- ** **Sterilization:** A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability (which, even though is a very low number, may never be zero).

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

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



including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

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

*** Supervision

- **1. Direct Supervision:** The supervising physician must be immediately available if needed, meaning physically present in the facility, and prepared to immediately conduct hands-on intervention if needed. However, the physician does not need to be in the room throughout the performance of the service.
- **2. General supervision:** The service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and maintain the necessary equipment and supplies is the physician's continuing responsibility.
- **3. Personal supervision:** A physician must be present in the room during the procedure.
- * Surgical Site Infection (SSI): An infection at the site of a surgical incision. The SSI may be superficial, deep, or extend to organs. Patients should be monitored for SSIs for thirty (30) days after surgery or procedures or three-hundred and sixty-five (365) days after implant placement.



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

TABLE 7-1 Design Parameters

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	RH (k), %	Design Temperature (I), °F/°C
SURGERY AND CRITICAL CARE							
Class B and C operating rooms, (m), (n), (o)	Positive	4	20	N/R	No	2030-60	68-75/20-24
Operating/surgical cystoscopic rooms, (m), (n), (o)	Positive	4	20	N/R	No	2030-60	68-75/20-24
Delivery room (Caesarean) (m), (n), (o)	Positive	4	20	N/R	No	2030-6 0	68-75/20-24
Treatment room (p)	N/R	2	6	N/R	N/R	2030-6 0	70-75/21-24
Trauma room (crisis or shock) (c)	Positive	3	15	N/R	No	2030-6 0	70-75/21-24
Laser eye room	Positive	3	15	N/R	No	2030-60	70-75/21-24
Class A Operating/Procedure room (o), (d)	Positive	3	15	N/R	No	2030-60	70-75/21-24
DIAGNOSTIC AND TREATMENT							
Gastrointestinal endoscopy procedure room	Positive	2	6	N/R	No	2030-6 0	68-73/20-23