

Medicare Rural Health Clinic (RHC) Accreditation Standards Manual

Version 3.3, Effective August 5, 2023

***American Association for Accreditation of Ambulatory Surgery Facilities***

QUAD A RHC Standards – © 2023

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# Survey Instructions

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

# Standards Structure

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

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

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

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

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

# Standards Book Layout

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

**ID:** This column contains the alphanumerical identifier for each standard.

**Standard:** This column contains the text for each standard.

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

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

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

# Scoring Compliance

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

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

**NOTES:**

Click or tap here to enter text.

**ECTION 1: BASIC MANDATES**

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **SUB-SECTION B: BASIC MANDATES** | | | | |
| **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. |  | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 3: SAFETY**

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **SUB-SECTION F: Exits** | | | | |
| **3-F-1** | Fire exit signs are posted and illuminated consistent with state, local, and/or NFPA codes and OSHA codes. |  | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **3-F-3** | There are sufficient emergency lights for exit routes and patient care areas in case of power failure. |  | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 5: IN CASE OF EMERGENCY**

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **SUB-SECTION D: Emergency Preparedness Plan** | | | | |
| **5-D-1** | The Provider/Supplier must comply with all applicable Federal, State, and local emergency preparedness requirements. The Provider/Supplier must establish and maintain an emergency preparedness program that meets the requirements of this section. | 491.12 Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-2** | Emergency plan: The Provider/Supplier must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two (2) years. | 491.12(a)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-3** | The plan must be based on and include a documented, facility- based and community-based risk assessment, utilizing an all- hazards approach. | 491.12(a)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-4** | The plan must include strategies for addressing emergency events identified by the risk assessment. | 491.12(a)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-5** | The plan must address patient population, including, but not limited to, the type of services the Provider/Supplier has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. | 491.12(a)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-7** | The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. | 491.12(a)(4)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **5-D-9** | Policies and procedures: The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, and the communication plan in standard 5-D-21. The policies and procedures must be reviewed and updated at least every two (2) years. | 491.12(b)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-11** | At a minimum, the policies and procedures must address safe evacuation from the Provider/Supplier. | 491.12(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-12** | Safe evacuation from the Provider/Supplier must include consideration of care and treatment needs of evacuees. | 491.12(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-13** | Safe evacuation from the Provider/Supplier must include staff responsibilities. | 491.12(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-15** | Safe evacuation from the Provider/Supplier must include identification of evacuation locations, such as appropriate placement of exit signs. | 491.12(b)(2)(iv)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-17** | At a minimum, the policies and procedures must address a means to shelter in place for patients, staff, and volunteers who remain in the Provider/Supplier. | 491.12(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-18** | At a minimum, the policies and procedures must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records. | 491.12(b)(4)(i)  Standard  491.12(b)(4)(ii)  Standard  491.12(b)(4)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **5-D-19** | At a minimum, the policies and procedures must address the use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency. | 491.12(b)(5)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-21** | Communication plan: The Provider/Supplier must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years. | 491.12.c Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-22** | The communication plan must include names and contact information for Staff, Entities providing services under arrangement, Patients' physicians, Volunteers, and Other Provider/Suppliers within the same Medicare type. | 491.12(c)(1)  Standard  491.12(c)(1)(i)  Standard  491.12(c)(1)(ii)  Standard  491.12(c)(1)(iii)  Standard  491.12(c)(1)(iv)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-23** | The communication plan must include contact information for Federal, state, tribal, regional, and local emergency preparedness staff and Other sources of assistance. | 491.12(c)(2)  Standard  491.12(c)(2)(i)  Standard  491.12(c)(2)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **5-D-24** | The communication plan must include primary and alternate means for communicating with Provider/Supplier's staff and Federal, State, tribal, regional, and local emergency management agencies. | 491.12(c)(3)  Standard  491.12(c)(3)(i)  Standard  491.12(c)(3)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-27** | The communication plan must include a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). | 491.12(c)(6)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-28** | The communication plan must include a means of providing information about the Provider/Supplier's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. | 491.12(c)(7)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-29** | Training and testing: The Provider/Supplier must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, policies and procedures in standard 5-D-9, and the communication plan in standard 5-D-21. The training and testing program must be reviewed and updated at least every two (2) years. | 491.12(d)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-30** | The training program must consist of initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. | 491.12(d)(1)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **5-D-31** | The training program must provide emergency preparedness training at least every two (2) years. | 491.12.d.1.ii  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-32** | The training program must maintain documentation of all emergency preparedness training. | 491.12(d)(1)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-33** | The training program must demonstrate staff knowledge of emergency procedures. | 491.12(d)(1)(iv)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-34** | If the emergency preparedness policies and procedures are significantly updated, the Provider/Supplier must conduct training on the updated policies and procedures. | 491.12.d.1.v  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-35** | The Provider/Supplier must conduct exercises to test the emergency plan at least annually. | 491.12(d)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-36** | The Provider/Supplier 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 Provider/Supplier experiences an actual natural or man- made emergency that requires activation of the emergency plan, the Provider/Supplier is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. | 491.12(d)(2)(1)  Standard  491.12(d)(2)(i)(A)  Standard  491.12(d)(2)(i)(B)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **5-D-37** | The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise as required by standard 5-D-36 is conducted, that may include, but is not limited to the following:   1. A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or 2. A mock disaster drill; or 3. 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. | 491.12(d)(2)(ii)  Standard  491.12(d)(2)(ii)(A)  Standard  491.12(d)(2)(ii)(B)  Standard  491.12(d)(2)(ii)(C)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-D-38** | The Provider/Supplier must analyze the Provider/Supplier's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the Provider/Supplier's emergency plan, as needed. | 491.12(d)(2)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: Emergency Preparedness Plan – Integrated Healthcare Systems** | | | | |
| **5-E-1** | If a Provider/Supplier is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the Provider/Supplier may choose to participate in the healthcare system's coordinated emergency preparedness program. | 491.12(e)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-2** | If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. | 491.12(e)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **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. | 491.12(e)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-4** | If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program. | 491.12(e)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-5** | If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 5-D-4, 5-D-5, and 5-D- 7. | 491.12(e)(4)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-7** | If elected, the unified and integrated emergency plan must also be based on and include a documented community-based risk assessment, utilizing an all-hazards approach. | 491.12(e)(4)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-8** | If elected, the unified and integrated emergency plan must also be based on and include a documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. | 491.12(e)(4)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **5-E-9** | If elected, the unified and integrated emergency preparedness program must include integrated policies and procedures that meet the requirements set forth in 5-D-9, a coordinated communication plan, and training and testing programs that meet the requirements in standards 5-D-21 and 5-D-29, respectively. | 491.12(e)(5)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

**SECTION 11: PERSONNEL**

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **SUB-SECTION E: Facility Staffing** | | | | |
| **11-E-5** | All individuals using the clinic must meet one of the following criteria:  1. A Doctor of Medicine certified or eligible for |  | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
|  | certification by one of the member boards of the |  |  |
|  | American Board of Medical Specialties (ABMS medical or |  |  |
|  | surgical specialty). |  |  |
|  | 2. A Doctor of Osteopathy certified or eligible for |  |  |
|  | certification by the American Osteopathic Association |  |  |
|  | Bureau of Osteopathic Specialists (AOABS). |  |  |
|  | 3. Physician Assistant |  |  |
|  | 4. Nurse Practitioner |  |  |
|  | 5. Nurse Midwife |  |  |
|  | 6. Psychologist |  |  |
|  | 7. State Licensed Mental Health Professional (Social |  |  |
|  | worker, Marriage and Family Therapist, Professional |  |  |
|  | Counselor) |  |  |

**SECTION 14: Rural Health Clinic (RHC)**

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **SUB-SECTION A: Compliance with Federal, State and Local Laws** | | | | |
| **14-A-1** | The rural health clinic and its staff are in compliance with applicable Federal, State, and local laws and regulations. | 491.4  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-A-2** | The rural health clinic is licensed pursuant to applicable State and local law. | 491.4(a)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-A-3** | The staff of the rural health clinic are licensed, certified or registered in accordance with applicable State and local laws. | 491.4(b)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION B: Location of Clinic** | | | | |
| **14-B-1** | Location of clinic. | 491.5  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-B-2** | The rural health clinic may be a permanent or mobile unit. | 491.5(a)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-B-3** | If the clinic is a permanent structure, the objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure. | 491.5(a)(3)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-B-4** | If the clinic is a mobile unit, the objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure, which has fixed, scheduled location(s). | 491.5(a)(3)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-B-5** | If the clinic services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic. | 491.5(a)(3)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION C: Physical Plant and Environment** | | | | |
| **14-C-1** | Physical plant and environment. | 491.6  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-C-2** | The clinic is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services. | 491.6(a)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-C-3** | The clinic has a preventive maintenance program to ensure that all essential mechanical, electric and patient- care equipment is maintained in safe operating condition. | 491.6(b)  Standard  491.6(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-C-4** | The clinic keeps the drugs and biologicals appropriately stored. | 491.6(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-C-5** | The clinic premises are kept clean and orderly. | 491.6(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION D: Organizational Structure** | | | | |
| **14-D-1** | Organizational structure. | 491.7  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-D-2** | The clinic is under the medical direction of a physician, and has a healthcare staff that knows and meets the basic requirements of QUAD A Section 14-E. | 491.7(a)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-D-3** | The clinic organizational policies and lines of authority and responsibilities are clearly set forth in writing. | 491.7(a)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-D-4** | The clinic clearly discloses the names and addresses of its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A–3). | 491.7(b)  Standard  491.7(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-D-5** | The clinic has clearly disclosed the name and address of the person principally responsible for directing the operation of the clinic. | 491.7(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-D-6** | The clinic has clearly disclosed the name and address of the person principally responsible for medical direction of the clinic. | 491.7(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION E: Staffing and Staff Responsibilities** | | | | |
| **14-E-1** | **Physician**   * As it pertains to the supervision, collaboration, and oversight requirements in sections 1861 (aa)(2)(B) and (aa)(3) of the Social Security Act; a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and * Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Social Security Act for specific limitations). | 491.2  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-E-2** | **Nurse Practitioner**  The clinic's nurse practitioner is currently licensed to practice in the state, and meets the State's requirements governing the qualifications of nurse practitioners. And meets one of the following conditions:   1. The clinic's nurse practitioner is currently certified as a primary care nurse practitioner by the America Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates. 2. The clinic's Nurse Practitioner has satisfactorily completed a formal one (1) academic year educational program that:    1. Prepares registered nurses to perform an expanded role in the delivery of primary care;    2. That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.    3. Awards a degree, diploma, or certificate to persons who successfully complete the program 3. The clinic's Nurse Practitioner has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements identified above in paragraph 2, and the clinic's Nurse Practitioner has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of the   subpart. | 491.2  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-E-3** | **Physician Assistant**  The Physician Assistant 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 primary care physicians. 2. The Physician assistant has satisfactorily completed a program for preparing physician's assistants that:    1. Was at least one academic year in length;    2. Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and    3. 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 primary care physicians for a total of 12 months during the 18- month period that ended on December 31, 1986. | 491.2  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-4** | Staffing and staff responsibilities. | 491.8  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-E-5** | The clinic has health care staff that includes one or more physicians, and one or more physician's assistants or nurse practitioners. | 491.8(a)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-6** | The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic, or under agreement with the clinic to carry out the responsibilities required under QUAD A Section 14-E. | 491.8(a)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-7** | The physician assistant, nurse practitioner, nurse- midwife, clinical social worker, or clinical psychologist member of the staff may be the owner, an employee of the clinic, or may furnish service under contract to the clinic. At least one physician assistant or nurse practitioner must be an employee of the clinic. | 491.8(a)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-8** | The clinic staff may include ancillary personnel who are supervised by the professional staff. | 491.8(a)(4)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-9** | The clinic staff is sufficient to provide essential services for the operation of the clinic. | 491.8(a)(5)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-10** | There is a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist available to furnish patient care services at all times the clinic operates, and a nurse practitioner or a physician assistant, or certified nurse- midwife is available to furnish patient care services at least 50 percent of the time the RHC operates. | 491.8(a)(6)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-E-11** | The clinic physician provides medical direction for the clinic's health care activities and consultation for, and medical supervision of, the health care staff. | 491.8(b)  Standard  491.8(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-12** | The clinic physician in conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's written policies and services provided to Federal program patients. | 491.8(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-13** | The clinic physician periodically reviews the clinic's patient records, provides medical orders, and provides medical patient care services to the patients of the clinic. | 491.8(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-14** | The physician assistant and the nurse practitioner members of the clinic's staff participate in the development, execution and periodic review of the written policies governing the services the clinic furnishes. | 491.8(c)  Standard  491.8(c)(1)  Standard  491.8(c)(1)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| [**14-E-15**](#_bookmark3) | The physician assistant and the nurse practitioner members of the clinic's staff participate with a physician in a periodic review of the patient's health records. | 491.8(c)(1)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| [**14-E-16**](#_bookmark3) | The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician: Provides services in accordance with the clinic's policies. | 491.8(c)(2)  Standard  491.8(c)(2)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| [**14-E-17**](#_bookmark3) | The physician assistant or nurse practitioner perform the following functions, to the extent they are not being performed by a physician: arranges for, or refers patients to, needed services that cannot be provided at the clinic. | 491.8(c)(2)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-E-18** | The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician: assure that adequate patient health records are maintained and transferred as required when patients are referred. | 491.8(c)(2)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION F: Provision of Services** | | | | |
| **14-F-1** | Provision of services. | 491.9  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-2** | All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws. | 491.9(a)  Standard  491.9(a)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-3** | The clinic is primarily engaged in providing outpatient health services and meets all other conditions of this subpart. | 491.9(a)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-4** | The clinic's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State Law. | 491.9(b)  Standard  491.9(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-F-5** | The clinic's policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners, and at least one member that is not a member of the clinic staff. | 491.9(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-6** | The clinic's policies include a description of the services the clinic furnished directly and those furnished through agreement or arrangement. | 491.9(b)(3)  Standard  491.9(b)(3)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-7** | The clinic's policies include guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic. | 491.9(b)(3)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-8** | The clinic's policies include rules for the storage, handling, and administration of drugs and biologicals. | 491.9(b)(3)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| [**14-F-9**](#_bookmark3) | The clinic's policies are reviewed at least biennially by the group of professional personnel identified in standard 14- F-5 and reviewed as necessary by the RHC. | 491.9(b)(4)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-10** | The clinic staff furnish those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system including medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions. | 491.9(c)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-F-11** | The clinic provides laboratory services in accordance with [part 493](https://www.ecfr.gov/cgi-bin/text-idx?SID=525692d826f5a09b3f3fbda654b887fd&mc=true&node=pt42.5.493&rgn=div5) of this chapter which implements the provisions of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient. | 491.9(a)(3)  Standard  491.9(c)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-12** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including chemical examinations of urine by stick or tablet method or both (including urine ketones). | 491.9(a)(3)  Standard  491.9(c)(2)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-13** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including Hemoglobin or hematocrit. | 491.9(a)(3)  Standard  491.9(c)(2)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-14** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including blood glucose. | 491.9(a)(3)  Standard  491.9(c)(2)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-15** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including examination of stool specimens for occult blood. | 491.9(a)(3)  Standard  491.9(c)(2)(iv)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-16** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including pregnancy tests. | 491.9(a)(3)  Standard  491.9(c)(2)(v)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-F-17** | The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including primary culturing for transmittal to a certified laboratory. | 491.9(a)(3)  Standard  491.9(c)(2)(vi)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-18** | The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biological commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids. | 491.9(c)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-19** | The clinic has current agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including inpatient hospital care. | 491.9(d)  Standard  491.9(d)(1)  Standard  491.9(d)(1)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-20** | The clinic has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere). | 491.9(d)(1)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-F-21** | The clinic has current agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to patients including additional and specialized diagnostic and laboratory services that are not available at the clinic. | 491.9(d)(1)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-F-22** | If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated. | 491.9(d)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION G: Patient Clinical Records** | | | | |
| **14-G-1** | Patient health records. | 491.10  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-2** | The clinic maintains a clinical record system in accordance with written policies and procedures. | 491.10(a)  Standard  491.10(a)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| [**14-G-3**](#_bookmark3) | The clinic has a designated member of the professional staff who is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized. | 491.10(a)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-4** | For each patient receiving health care services, the clinic maintains a record that includes identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient. | 491.10(a)(3)  Standard  491.10(a)(3)(i)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-5** | For each patient receiving health care services, the clinic maintains a record that includes reports of physical examinations, diagnostic and laboratory test results, and consultative findings. | 491.10(a)(3)(ii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-G-6** | For each patient receiving health care services, the clinic maintains a record that includes all physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress. | 491.10(a)(3)(iii)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-7** | For each patient receiving health care services, the clinic maintains a record that includes signatures of the physician or other health care professional. | 491.10(a)(3)(iv)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-8** | The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use. | 491.10(b)  Standard  491.10(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-9** | The clinic has written policies and procedures in place that govern the use and removal of records from the clinic and the conditions for release of information. | 491.10(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-10** | The clinic has written policies and procedures in place requiring the patient's written consent for release of information not authorized to be released without such consent. | 491.10(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-G-11** | The clinic has written policies and procedures in place for retention of records to be retained for at least six (6) years from date of last entry, and longer if required by State statute. | 491.10(c)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **SUB-SECTION H: Program Evaluation** | | | | |
| **14-H-1** | Program evaluation. | 491.11  Condition | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-H-2** | The clinic has carried out, or arranged for, a biennial evaluation of its total program.  *Compliance Note***:** A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(a)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-H-3** | The clinic conducts an evaluation, including a review of the utilization of clinic services, including at least the number of patients served and the volume of services.  *Compliance Note***:** A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(b)  Standard  491.11(b)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-H-4** | The clinic conducts an evaluation, including a representative sample of both active and closed clinical records.  *Compliance Note*: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(b)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-H-5** | The clinic conducts an evaluation, including a review of the clinic's health care policies.  *Compliance Note*: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(b)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-H-6** | The clinic conducts an evaluation to determine whether the utilization of services were appropriate.  *Compliance Note*: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(c)  Standard  491.11(c)(1)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-H-7** | The clinic conducts an evaluation to determine whether the established policies were followed.  *Compliance Note***:** A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(c)(2)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

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| **ID** | **Standard** | **CMS Ref** | **Score** | **Findings/Comments** |
| **14-H-8** | The clinic conducts an evaluation to determine whether any changes are needed.  *Compliance Note*: A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(c)(3)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |
| **14-H-9** | The clinic staff considers the findings of the evaluation and has taken correct action if necessary.  *Compliance Note***:** A facility operating for less than one year or in the start-up phase may satisfy the standard without having conducted a program evaluation as long as the facility has a written plan specifying the party responsible for conducting the program evaluation, how the evaluation is to be conducted, a time frame for completing the evaluation, and the areas of operation to be covered by the evaluation. | 491.11(d)  Standard | * Compliant * Deficient | Enter observations of non-compliance, comments or notes here. |

**GLOSSARY**

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

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

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

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

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

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**APPENDIX 2**

**Purpose and Scope**

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

**Certification Procedures**

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

**APPENDIX 3**

**Location of Clinic**

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

**Exceptions:**

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

A private, nonprofit facility that meets all other conditions of this subpart except for location

in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served. **[*42 CFR 491.5(b)(2)*]**

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

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

1. Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau. ***[42 CFR 491.5(c)(1)]***
2. Excluded from the rural area classification are:
   1. Central cities of 50,000 inhabitants or more; ***[42 CFR 491.5(c)(2)(i)]***
   2. Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities; ***[42 CFR 491.5(c)(2)(ii)]***
   3. Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban. ***[42 CFR 491.5(c)(2)(iii)]***
3. Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural. ***[42 CFR 491.5(c)(3)]***

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

1. The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are: ***[42 CFR 491.5(d)(1)]***
   1. The ratio of primary care physicians practicing within the area to the resident population; ***[42 CFR 491.5(d)(1)(i)]***
   2. The infant mortality rate; ***[42 CFR 491.5(d)(1)(ii)]***
   3. The percent of the population 65 years of age or older; ***[42 CFR 491.5(d)(1)(iii)]*** and
   4. The percent of the population with a family income below the poverty level. ***[42 CFR 491.5(d)(1)(iv)]***
2. The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are: ***[42 CFR 491.5(d)(1)]***
   1. The area served is a rational area for the delivery of primary medical care services; ***[42 CFR 491.5(d)(1)(i)]***
   2. The ratio of primary care physicians practicing within the area to the resident

population; ***[42 CFR 491.5(d)(1)(ii)] and***

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

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

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

***[42 CFR 491.5(e)(2)]***



# AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES

QUAD A Office:

7500 Grand Avenue, Suite 200 Gurnee, IL 60031, USA

TOLL-FREE: +1-888-545-5222

PHONE: +1-847-775-1970

FAX: +1-847-775-1985

EMAIL: [info@QUAD A.org](mailto:info@aaaasf.org)

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