RHC ACCREDITATION
Standards and Checklist

For Accreditation of Rural Health Clinics
AAAASF/ RHC
Standards and Checklists Manual
Version 2.3

© 2020 Publication
American Association for Accreditation of Ambulatory Surgery Facilities, Inc
The Accreditation Program

The Rural Health Clinic Accreditation Program was developed by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF). The RHC Accreditation Program certifies that an accredited clinic meets nationally recognized standards. The accreditation program is conducted by Physicians, Nurses, and Physician Assistants who determine the standards under the direction of the Board of Directors of AAAASF. The AAAASF strives for the highest standards of excellence for its facilities by regularly revising and updating its requirements for patient safety and quality of care.

Basic Mandates

- Changes in clinic ownership must be reported to the AAAASF Office within thirty (30) days.

- Any death occurring in an accredited clinic, or any death occurring within thirty (30) days of a surgical procedure performed in an accredited clinic, must be reported to the AAAASF office within five (5) business days after the clinic is notified or otherwise becomes aware of that death. In the event of a death occurring within thirty (30) days of a patient being seen in an AAAASF accredited clinic, an unannounced inspection may be done by a senior inspector.

- All individuals using the clinic must meet one of the following criteria:
  1. A Doctor of Medicine certified or eligible for 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)
**Inspection**

A clinic is inspected every three years. All RHC Accreditation Program inspectors are trained by AAAASF. Inspectors have a working familiarity with rural health clinics. The clinic inspector will review any deficiencies with the clinic director and forward the Standards and Checklist answer sheet to the AAAASF Office. To be accredited by AAAASF, a clinic must meet every standard.

**Self-Evaluation**

A clinic is evaluated by the clinic director each year between inspections and the Standards and Checklist answer sheet is sent to the AAAASF Office. A clinic’s RHC accreditation remains valid if it continues to meet every standard.

**Denial or Loss of Accreditation**

The AAAASF may deny or revoke accreditation of a clinic if the clinic fails to satisfy every standard. If any medical professional providing services at the clinic:

- Has had their privileges restricted or limited by any hospital related to lack of clinical competence, ethical issues
- Has been found to be in violation of the Code of Ethics of any professional society or association of which they are a member.
- Has had their right to practice limited, suspended, terminated or otherwise affected by any state, province, or country, or if they have been disciplined by any licensing authority.
- Non-reporting of any of the above to the AAAASF office.

**Hearing**

Any clinic whose accreditation has been revoked or denied by the AAAASF has the right to a Hearing at which it may present such information as it deems advisable to show that it has satisfied the requirements for accreditation. The Hearing process is described in the AAAASF Bylaws available from the AAAASF Office.
Emergency Suspension or Emergency Probation

The AAAASF may place a clinic on Emergency Suspension or Emergency Probation status upon receiving information that a state board has taken action, or begun formal proceedings which may result in it taking action against a license of a practitioner at the clinic, or the Board of Directors determining that the agency may no longer meet AAAASF Standards for accreditation. A clinic that has been placed on Emergency Suspension or Emergency Probation status will remain in such status pending an expedited investigation and possible Hearing conducted in accordance with AAAASF procedures available from the AAAASF Office.

Important Notice

Maximal patient safety has always been our guiding concern. We are proud that our Standards may be considered the strongest of any agency that accredits rural health clinics and that many consider them to be the Gold Standard. We recognize, however, that they need to be part of a living document, and we continually re-evaluate and revise these Standards in the light of medical advances and changing legislative guidelines. The AAAASF RHC Accreditation Program requires 100% compliance with each Standard to become and remain accredited. There are no exceptions. However, when a Standard refers to appropriate or proper or adequate, reasonable flexibility and room for individual consideration by the inspector is permitted as long as patient and staff safety remain uncompromised.
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**Policy for Survey Medical Record Review**

Medical record review is conducted as part of the Medicare survey process. The lead surveyor must ensure that a random sample of medical records is reviewed. The following criteria must be met when performing medical record review during a site survey:

The clinic is required to produce a log or other record of closed cases for the previous six month period and the lead surveyor will select a sample of medical records to review. A sample of both open and closed cases must be reviewed.

Record review should include a random sample from each of both providers’ active and discharged cases.

The sample selected must represent a cross section of the cases performed at the clinic and include both Medicare beneficiaries and non-Medicare patients.

The minimum number of records selected for review is 20 for a clinic with a monthly case volume exceeding 50 and 10 for lower volume clinics. To avoid undue financial hardship for initial (start up) clinic sites, the minimum number of case file records required to be selected by the surveyor for review is no more than 5 (five) records total. Please note: the number of records reviewed should be determined by case volume not patient visits. The total number of records within the six month case period must be noted on the review form. If deficient practices are noted during the records review, the survey team should request additional record samples to substantiate the findings documented from the initial sample.

A Medical Record Review Form is provided to the survey team by AAAASF. The review form must be completed for ALL records that are reviewed with findings noted. If the team reviews additional records, the team must copy the form and document every record that was included in the sample review. The total number of medical records reviewed must be documented on the form to ensure that the policy has been adhered to.

**Policy for Survey Personnel Record Review**

The clinic must produce a complete list of all employees. The lead surveyor must ensure that a random sample of personnel records is reviewed.

The minimum number of records selected for review is 50% of the total number of personnel records. If deficient practices are noted during the records review, the survey team should request additional record samples to substantiate the findings documented from the initial sample.

Throughout the review process, if an egregious number of deficient practices are noted, the survey team must document whether the deficiencies constitute a condition level area of non-compliance.
Surveyor Instructions:

Citation

Include the facts and findings relevant to the deficient practice must answer the questions: who, what, where, when, and how. Illustrate the entity’s noncompliance with the requirement. The deficiency citation must clearly and legibly explain how the entity fails to comply with the regulatory requirements, not how it fails to comply with any guidelines for the interpretation of those requirements. Wherever possible, supply a numerator and denominator to demonstrate how systemic a deficiency is, for example “4/6 Medical records failed to include an informed consent”. Refer to the CMS Principles of Documentation for further instruction.

The citation must include a determination of whether the deficiency constitutes Standard or Condition Level Noncompliance. Condition level noncompliance is substantial noncompliance that requires additional surveys to ensure compliance before can be recommended or approved.

Official Forms

Surveyors may not submit custom surveyor materials as the surveyor report to the AAAASF office. The requirement for surveyor report submission is specific to the official AAAASF surveyor materials, which must be completed in full according to AAAASF surveyor guidelines and policies. Any custom materials are only considered to be in support of or as supplements to the official materials. All forms must be completed in ink.

When scoring, please use a clear check mark (✓) to indicate your scoring decision.

Record Review

The survey process requires the completion of two record review components, personnel record review and clinical record review. The AAAASF staff has gathered the appropriate information, such as the monthly case load and number of employees, from the facility to establish the facility specific requirements for both record review components. Please review, at a minimum, the number of record reviews indicated on the review form provided in this manual. You may ask for additional records to facilitate a determination of whether a deficient practice is a rare occurrence or a systemic problem. Please make additional copies of forms as needed and document your findings.

When completing review worksheets simply fill in the circle corresponding to the appropriate answer to document your findings. Please refrain from using symbols and other notes. For any file component that is noncompliant for one or more files, the corresponding standard must be cited as deficient and a deficiency form must be completed.

When conducting the Personnel Record Review please also verify that the number of facility employees matches the number listed on the Personnel Record Review Form.
Error Corrections

The AAAASF Surveyor Manual is an official record as such all surveyor notations must be made in ink, corrections and revisions must also be made consistent with AAAASF procedures. Any errors or revisions to narrative or scoring must be corrected using a single horizontal strikethrough with the initials of the surveyor and date of the revision. Do not use liquid paper, scribble out, or “X” over errors or revisions.

Example: 100.010.065 ☑️ Compliant ☑️ Deficient

Extension Site Surveys (OPT Only)

When conducting a survey for an Extension Location, please fully complete the surveyor manual and all appropriate worksheets. If a standard pertains to a function or service not provided at the particular site being surveyed, mark the standard as “Compliant” in the Surveyor Manual for that location. For example if the site does not employ an occupational therapist, all standards relating to the qualifications and duties of an occupational therapist must be marked “Compliant”.

JD
1/1/2014
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**Version 2.2**

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Section 100: § 491.1 Purpose and scope

The clinic meets the purpose and scope to qualify for Medicare reimbursement.

The CMS regulatory text is as follows:

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics [or FQHCs (N/A)] 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).
The clinic staff is providing direct services to patients.

1. 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.

- 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.

- The clinic's Nurse Practitioner has satisfactorily completed a formal one (1) academic year educational program that:

  - Prepares registered nurses to perform an expanded role in the delivery of primary care;

  - That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.

  - And a component of supervised clinical practice that awards a degree, diploma, or certificate to persons who successfully complete the program;

Or

- 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 of 200.10.35, 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.

2. 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).
3. Physician assistant

- The Physician assistant meets the applicable State requirements governing the qualifications for assistants to primary care physicians.

- The Physician assistant is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

- The Physician assistant has satisfactorily completed a program for preparing physician's assistants that was at least one academic year in length.

- The Physician assistant has satisfactorily completed a supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care.

- The Physician assistant has satisfactorily completed a supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care which was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

- 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.

To be pre-qualified by the corresponding CMS Regional Office:

1. The clinic is located in a rural area that is not delineated as an urbanized area by the Bureau of the Census.

2. The clinic is located in a rural area designated as a shortage area, and the clinic is meeting all other requirements including verification that it is not functioning as a rehabilitation agency, or functioning as a facility primarily for the treatment of mental diseases.

3. The clinic meets the definition of a shortage area defined as a shortage of personal health services or a shortage of primary medical care manpower as defined by the Public Health Service Act.

4. 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).

491.2 Condition
Section 300: § 491.3 Certification procedures

300.010.005

___ Compliant ______ Deficient

The CMS regulatory text is as follows:

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart X 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.

491.3 Condition
400.010 Section 400: § 491.4 Compliance with Federal, State and local laws

400.010.010 ___ Compliant ______ Deficient

The rural health clinic and its staff are in compliance with applicable Federal, State, and local laws and regulations.

*The CMS regulatory text is as follows:*

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic [or FQHC (N/A)] and its staff are in compliance with applicable Federal, State and local laws and regulations.

491.4 Condition

400.010.015 ___ Compliant ______ Deficient

The rural health clinic is licensed pursuant to applicable State and local law.

*The CMS regulatory text is as follows:*

(a) Licensure of clinic [or center (N/A)]. The clinic [or center (N/A)] is licensed pursuant to applicable State and local law.

491.4.a Standard

400.010.020 ___ Compliant ______ Deficient

The staff of the rural health clinic are licensed, certified or registered in accordance with applicable State and local laws.

*The CMS regulatory text is as follows:*

(b) Licensure, certification or registration of personnel. Staff of the clinic [or center (N/A)] are licensed, certified or registered in accordance with applicable State and local laws.

491.4.b Standard
500 LOCATION OF CLINIC

500.010 Section 500: § 491.5 Location of clinic

___ Compliant ______ Deficient

491.5 Condition

500.010.010 ___ Compliant ______ Deficient

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

The location of the rural health clinic meets all basic requirements, and is in a rural area that is designated as a shortage area.

The CMS regulatory text is as follows:

§ 491.5 Location of clinic.

(a) Basic requirements. (1) An RHC is located in a rural area that is designated as a shortage area.

491.5.a.1 Standard

491.5.a Standard

500.010.020 ___ Compliant ______ Deficient

The rural health clinic may be a permanent or mobile unit.

The CMS regulatory text is as follows:

(3) Both the RHC [and the FQHC (N/A)] may be permanent or mobile units.

491.5.a.3 Standard

500.010.025 ___ Compliant ______ Deficient

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.

The CMS regulatory text is as follows:

(i) Permanent unit. The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic [or center (N/A)] are housed in a permanent structure.

491.5.a.3.(i) Standard
500 LOCATION OF CLINIC

500.010.030

___ Compliant ______ Deficient

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).

*The CMS regulatory text is as follows:*

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic [or center (N/A)] are housed in a mobile structure, which has fixed, scheduled location(s).

491.5.a.3.(ii) Standard

500.010.035

___ Compliant ______ Deficient

If the clinic is a permanent structure located in more than one location, each unit is independently considered for approval as a rural health clinic. Are there more than one locations for this clinic?

*The CMS regulatory text is as follows:*

(iii) *Permanent unit in more than one location.* If clinic [or center (N/A)] services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic [or for approval as an FQHC (N/A)].

491.5.a.3.(iii) Standard

500.010.045

___ Compliant ______ Deficient

AAAASF evaluates whether an RHC meets the eligibility requirements at the time of initial survey by collecting a current Health Professional Shortage Area (HPSA) or Medically Underserved Area (MUA) designation and evidence that the clinic is located in a non-urbanized area via US Census Bureau Reports. AAAASF does not assess if the facility meets the definition of a rural, shortage area as part of the resurvey process. The CMS Regional Office makes the final determination:

(b) *Exceptions.* (1) 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.

491.5.b Standard
491.5.b.1 Standard
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### 500.010.050

___ Compliant ______ Deficient

AAAASF will assess whether a clinic meets the requirements for a clinic operating as of July 1, 1977 based on consultation with the State Agency and Regional Office. The CMS Regional Office makes the final determination based on the following materials provided by AAAASF:

- A description of the geographic boundaries of the facility’s service area
- Information developed through consultation with the PHS RO staff about whether the area, or any portion of the area, had ever been reviewed for designation under any of the applicable sections of the PHS Act;
- Identification of any designated population group or institution in the facility’s service area;
- Information secured from the appropriate Health Systems Agency and the State Health Planning and Development Agency about the primary care resources available in the facility’s service area;
- Information about any planning, developmental, or operating funds awarded to the facility by the county, State, or Federal Government to assist in providing greater access to health care in the area;
- Information about the factors considered in determining where the facility was to be located; and
- Any additional information the SA or RO feels is relevant.

(2) 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.

### 491.5.b.2 Standard

___ Compliant ______ Deficient

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

### 491.5.b.3 Standard
### 500.010.065

AAAASF evaluates whether an RHC meets the eligibility requirements for designation as rural by verifying that the clinic is located in an area not delineated as urbanized on official reports of most recent census from the US Census Bureau. The CMS Regional Office makes the final determination:

(c) **Criteria for designation of rural areas.** (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

491.5.c Standard
491.5.c.1 Standard

### 500.010.070

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(2) Excluded from the rural area classification are:

491.5.c.2 Standard

### 500.010.075

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(i) Central cities of 50,000 inhabitants or more;

491.5.c.2.(i) Standard

### 500.010.080

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(ii) 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;

491.5.c.2.(ii) Standard
AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

491.5.c.2.(iii) Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

491.5.c.3 Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(d) Criteria for designation of shortage areas. (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

491.5.d Standard
491.5.d.1 Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(i) The ratio of primary care physicians practicing within the area to the resident population;

491.5.d.1.(i) Standard
AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(ii) The infant mortality rate;

491.5.d.1.(ii) Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(iii) The percent of the population 65 years of age or older; and

491.5.d.1.(iii) Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(iv) The percent of the population with a family income below the poverty level.

491.5.d.1.(iv) Standard

(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:

491.5.d.2 Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(i) The area served is a rational area for the delivery of primary medical care services;

491.5.d.2.(i) Standard
AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

491.5.d.2.(ii) Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(iii) The primary medical care manpower in contiguous areas is over utilized, excessively distant, or inaccessible to the population in this area.

491.5.d.2.(iii) Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(e) Medically underserved population. A medically underserved population includes the following:

491.5.e Standard

AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

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

491.5.e.1 Standard
AAAASF will evaluate whether an RHC meets the eligibility requirements. The CMS Regional Office makes the final determination:

(2) A population group that is designated by PHS as having a shortage of personal health services.

491.5.e.2 Standard
600.010  **Section 600: § 491.6 Physical plant and environment**

___ Compliant ______ Deficient

491.6 Condition

600.010.005  ___ Compliant ______ Deficient

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.

*The CMS regulatory text is as follows:*

**§ 491.6 Physical plant and environment.**

(a) *Construction.* The clinic [or center (N/A)] 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

600.010.015  ___ Compliant ______ Deficient

The clinic has a preventive maintenance program to ensure that all essential mechanical, electric and patient-care equipment is maintained in safe operating condition.

*The CMS regulatory text is as follows:*

(b) *Maintenance.* The clinic [or center (N/A)] has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

491.6.b.1 Standard

491.6.b Standard
600.010.020

___ Compliant  ______ Deficient

The clinic keeps the drugs and biologicals appropriately stored.

*The CMS regulatory text is as follows:*

(2) Drugs and biologicals are appropriately stored; and

**491.6.b.2 Standard**

600.010.025

___ Compliant  ______ Deficient

The clinic premises are kept clean and orderly.

*The CMS regulatory text is as follows:*

(3) The premises are clean and orderly.

**491.6.b.3 Standard**

600.010.035

___ Compliant  ______ Deficient

The clinic assures the safety of patients in case of nonmedical emergencies by training staff to handle emergencies.

600.010.040

___ Compliant  ______ Deficient

The clinic displays exit signs in appropriate locations.
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<td>600.010.045</td>
<td>___ Compliant ______ Deficient</td>
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The clinic takes other appropriate safety measures consistent with the particular conditions of the area in which the clinic is located.
**Section 700: § 491.1 Organizational structure**

___ Compliant      ______ Deficient

491.7 Condition

The clinic is under the medical direction of a physician, and has a healthcare staff that knows and meets the basic requirements of CMS 42 CFR § 491.8 (AAAASF RHC Standards Section 800.010).

The CMS regulatory text is as follows:

§ 491.7 Organizational Structure.

(a) Basic requirements. (1) The clinic [or center (N/A)] is under the medical direction of a physician, and has a health care staff that meets the requirements of §491.8.

491.7.a Standard
491.7.a.1 Standard

The clinic organizational policies and lines of authority and responsibilities are clearly set forth in writing.

The CMS regulatory text is as follows:

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

491.7.a.2 Standard
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).

*The CMS regulatory text is as follows:*

(b) Disclosure. The clinic [or center (N/A)] discloses the names and addresses of:

(1) 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

The clinic has clearly disclosed the name and address of the person principally responsible for directing the operation of the clinic.

*The CMS regulatory text is as follows:*

(2) The person principally responsible for directing the operation of the clinic [or center (N/A)]; and

491.7.b.2 Standard

The clinic has clearly disclosed the name and address of the person principally responsible for medical direction of the clinic.

*The CMS regulatory text is as follows:*

(3) The person responsible for medical direction.

491.7.b.3 Standard
800 STAFFING AND STAFF RESPONSIBILITIES

800.010 Section 800: § 491.8 Staffing and staff responsibilities

___ Compliant      ______ Deficient

491.8 Condition

800.010.010 ___ Compliant      ______ Deficient

The clinic has health care staff that includes one or more physicians, and one or more physician's assistants or nurse practitioners.

The CMS regulatory text is as follows:

§ 491.8 Staffing and staff responsibilities.

(a) Staffing. (1) The clinic [or center (N/A)] has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

491.8.a Standard

491.8.a.1 Standard

800.010.015 ___ Compliant      ______ Deficient

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 42 CFR 491.8 [AAAASF Standards Section 800].

The CMS regulatory text is as follows:

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic [or center (N/A)], or under agreement with the clinic [or center (N/A)] to carry out the responsibilities required under this section.

491.8.a.2 Standard
## STAFFING AND STAFF RESPONSIBILITIES

### 800.010.020

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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.

*The CMS regulatory text is as follows:*

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic [or center (N/A)], or may furnish services under contract to the clinic [or center(N/A)]. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

### 491.8.a.3 Standard

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<th>Compliant</th>
<th>Deficient</th>
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### 800.010.025

The clinic staff may include ancillary personnel who are supervised by the professional staff.

*The CMS regulatory text is as follows:*

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

### 491.8.a.4 Standard

<table>
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<th>Compliant</th>
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### 800.010.030

The clinic staff is sufficient to provide essential services for the operation of the clinic.

*The CMS regulatory text is as follows:*

(5) The staff is sufficient to provide the services essential to the operation of the clinic [or center (N/A)].

### 491.8.a.5 Standard
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 is available to furnish patient care services at least 50 percent of the time the clinic operates.

*The CMS regulatory text is as follows:*

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic [or center (N/A)] operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 50 percent of the time the clinic operates.

491.8.a.6 Standard

The clinic physician provides medical direction for the clinic's health care activities and consultation for, and medical supervision of, the health care staff.

*The CMS regulatory text is as follows:*

(b) *Physician responsibilities.* The physician performs the following:

(1) [Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, (N/A)] provides medical direction for the clinic’s [or center’s (N/A)] health care activities and consultation for, and medical supervision of, the health care staff.
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.

*The CMS regulatory text is as follows:*

(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic’s [or center’s (N/A)] written policies and the services provided to Federal program patients.

491.8.b.2 Standard

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.

*The CMS regulatory text is as follows:*

(3) Periodically reviews the clinic's [or center's (N/A)] patient records, provides medical orders, and provides medical care services to the patients of the clinic [or center (N/A)].

491.8.b.3 Standard

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.

*The CMS regulatory text is as follows:*

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic [or center (N/A)] furnishes;

491.8.c Standard
491.8.c.1.(i) Standard
491.8.c.1 Standard
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.

*The CMS regulatory text is as follows:*

(ii) Participate with a physician in a periodic review of the patients' health records.

491.8.c.1.(ii) Standard

---

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.

*The CMS regulatory text is as follows:*

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's [or center's (N/A)] policies;

491.8.c.2.(i) Standard

491.8.c.2 Standard

---

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.

*The CMS regulatory text is as follows:*

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic [or center (N/A)]; and

491.8.c.2.(ii) Standard
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.

*The CMS regulatory text is as follows:*

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

491.8.c.2.(iii) Standard
### Section 900: § 491.9 Provision of services

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<td>491.9 Condition</td>
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</table>

#### 900.010.010

All services offered by the clinic are furnished in accordance with applicable Federal, State, and local laws.

*The CMS regulatory text is as follows:*

> § 491.9  Provision of services.

(a) Basic requirements. (1) All services offered by the clinic [or center (N/A)] are furnished in accordance with applicable Federal, State, and local laws; and

#### 900.010.015

All services offered by the clinic are primarily engaged in providing outpatient health services meeting all other applicable conditions.

*The CMS regulatory text is as follows:*

> (2) The clinic [or center (N/A)] is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

#### 900.010.020

*The CMS regulatory text is as follows:*

> (3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs[, but do not apply to FQHCs N/A].
The clinic’s health care services are furnished in accordance with appropriate written policies which are consistent with applicable State Law.

*The CMS regulatory text is as follows:*

(b) *Patient care policies.* (1) The clinic’s [or center’s (N/A)] 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

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.

*The CMS regulatory text is as follows:*

(2) The 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. At least one member is not a member of the clinic or center staff.

491.9.b.2 Standard

The clinic's policies include a description of the services the clinic furnished directly and those furnished through agreement or arrangement.

*The CMS regulatory text is as follows:*

(3) The policies include:

(i) A description of the services the clinic [or center (N/A)] furnishes directly and those furnished through agreement or arrangement.

491.9.b.3 Standard
491.9.b.3.(i) Standard
900.010.050  
___ Compliant     ______ Deficient

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.

*The CMS regulatory text is as follows:*

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic [or center (N/A)].

491.9.b.3.(ii Standard

900.010.060  
___ Compliant     ______ Deficient

The clinic's policies include rules for the storage, handling, and administration of drugs and biologicals.

*The CMS regulatory text is as follows:*

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

491.9.b.3.(iii Standard

900.010.065  
___ Compliant     ______ Deficient

The clinic's policies are reviewed at least biennially by the group of professional personnel reviewed as necessary by the clinic.

*The CMS regulatory text is as follows:*

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

491.9.b.4 Standard
**PROVISION OF SERVICES**

900.010.075  
___ Compliant   ______ Deficient

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.

*The CMS regulatory text is as follows:*

(c) Direct services — (1) General. The clinic [or center (N/A)] staff furnishes 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. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

491.9.c Standard  
491.9.c.1 Standard

900.010.080  
___ Compliant   ______ Deficient

The clinic provides laboratory services which implements the provisions of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including chemical examinations of urine by stick or tablet method or both (including urine ketones).

*The CMS regulatory text is as follows:*

(2) Laboratory. These requirements apply to RHCs [but not to FQHCs (N/A)]. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

491.9.c.2 Standard

900.010.085  
___ Compliant   ______ Deficient

The clinic provides laboratory services which implements the provisions of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including chemical examinations of urine by stick or tablet method or both (including urine ketones).

*The CMS regulatory text is as follows:*

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);

491.9.c.2.(i) Standard
900.010.090  ___ Compliant   ______ Deficient

The clinic provides basic laboratory services which implements the provision 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, including Hemoglobin or hematocrit.

*The CMS regulatory text is as follows:*

(ii) Hemoglobin or hematocrit;
491.9.c.2.(ii) Standard

900.010.095  ___ Compliant   ______ Deficient

The clinic provides basic laboratory services which implements the provisions of section 353 of the Public Health Service Act wherein the RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including blood glucose.

*The CMS regulatory text is as follows:*

(iii) Blood glucose;
491.9.c.2.(iii) Standard

900.010.100  ___ Compliant   ______ Deficient

The clinic provides basic laboratory services which implement the provisions for 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, including examination of stool specimens for occult blood.

*The CMS regulatory text is as follows:*

(iv) Examination of stool specimens for occult blood;
491.9.c.2.(iv) Standard

900.010.105  ___ Compliant   ______ Deficient

The clinic provides basic laboratory services which implement the provision 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, including pregnancy tests.

The CMS regulatory text is as follows:

(v) Pregnancy tests; and
491.9.c.2.(v) Standard
The clinic provides basic laboratory services which implement the provision 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, including primary culturing for transmittal to a certified laboratory.

*The CMS regulatory text is as follows:*

(vi) Primary culturing for transmittal to a certified laboratory.

491.9.c.2.(vi) Standard

The clinic provides medical emergency procedures as a first response to common life threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

*The CMS regulatory text is as follows:*

(3) *Emergency.* The clinic [or center (N/A)] provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

491.9.c.(3 Standard

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.

*The CMS regulatory text is as follows:*

(d) *Services provided through agreements or arrangements.* (1) The clinic [or center (N/A)] has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

491.9.d Standard
491.9.d.1 Standard
### 900.010.130

**__Compliant ______ Deficient**

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.

*The CMS regulatory text is as follows:*

(i) Inpatient hospital care;

491.9.d.1.(i) Standard

### 900.010.135

**__Compliant ______ Deficient**

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 such as a physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere).

*The CMS regulatory text is as follows:*

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

491.9.d.1.(ii) Standard

### 900.010.140

**__Compliant ______ Deficient**

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 such as additional and specialized diagnostic and laboratory services that are not available at the clinic.

*The CMS regulatory text is as follows:*

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic [or center (N/A)].

491.9.d.1.(iii) Standard
If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated.

*The CMS regulatory text is as follows:*

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic [or center (N/A)] are being accepted and treated.

491.9.d.2 Standard
Section 1000: § 491.10 Patient health records

---

1000.010

___ Compliant      ______ Deficient

491.10 Condition

1000.010.005

___ Compliant      ______ Deficient

The clinic maintains a clinical record system in accordance with written policies and procedures.

*The CMS regulatory text is as follows:*

§ 491.10 Patient health records.

(a) Records System. (1) The clinic [or center (N/A)] maintains a clinical record system in accordance with written policies and procedures.

491.10.a Standard

491.10.a.1 Standard

1000.010.010

___ Compliant      ______ Deficient

The clinic has a designated member of the professional staff who is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

*The CMS regulatory text is as follows:*

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

491.10.a.2 Standard
### 1000.010.020

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<td>Compliant</td>
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<td>Deficient</td>
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The clinic maintains a record for each patient receiving health care services, 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.

*The CMS regulatory text is as follows:*

(3) For each patient receiving health care services, the clinic (or center (N/A)) maintains a record that includes, as applicable:

(i) 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

1000.010.025

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<td>Deficient</td>
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</table>

The clinic maintains a record for each patient containing reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

*The CMS regulatory text is as follows:*

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

#### 491.10.a.3.(ii) Standard

1000.010.030

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<th>Classifications</th>
<th>Status</th>
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<td>Compliant</td>
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<tr>
<td>Deficient</td>
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</table>

The clinic maintains a record for each patient containing all physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress.

*The CMS regulatory text is as follows:*

(iii) 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
<table>
<thead>
<tr>
<th>Section</th>
<th>Compliance Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000.010.035</td>
<td>Compliant</td>
<td>The clinic maintains a record for each patient containing signatures of the physician or other health care professional.</td>
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<tr>
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<td></td>
<td>The CMS regulatory text is as follows:</td>
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<td>(iv) Signatures of the physician or other health care professional.</td>
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<td>491.10.a.3.(iv) Standard</td>
</tr>
<tr>
<td>1000.010.045</td>
<td>Compliant</td>
<td>The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.</td>
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<td>The CMS regulatory text is as follows:</td>
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<td>(b) Protection of record information. (1) The clinic [or center (N/A)] maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.</td>
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<td>491.10.b Standard</td>
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<td>491.10.b.1 Standard</td>
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<tr>
<td>1000.010.050</td>
<td>Compliant</td>
<td>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.</td>
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<td>The CMS regulatory text is as follows:</td>
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<td>(2) Written policies and procedures govern the use and removal of records from the clinic [or center (N/A)] and the conditions for release of information.</td>
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<td>491.10.b.2 Standard</td>
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<td>1000.010.055</td>
<td>___ Compliant       ______ Deficient</td>
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<tr>
<td>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.</td>
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<tr>
<td>The CMS regulatory text is as follows:</td>
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<tr>
<td>(3) The patient's written consent is required for release of information not authorized to be released without such consent.</td>
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<td>491.10.b.3 Standard</td>
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<tr>
<th>1000.010.060</th>
<th>___ Compliant       ______ Deficient</th>
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<tr>
<td>The clinic has written policies and procedures in place for retention of records to be retained for at least 6 years from date of last entry, and longer if required by State statute.</td>
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<tr>
<td>The CMS regulatory text is as follows:</td>
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<tr>
<td>(c) Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute.</td>
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<td>491.10.c Standard</td>
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</table>
Section 1100: § 491.11 Program evaluation

___ Compliant      ______ Deficient

491.11 Condition

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.

The CMS regulatory text is as follows:

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.

491.11.a Standard
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<th>1100</th>
<th>PROGRAM EVALUATION</th>
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<tr>
<td>1100.010.015</td>
<td>___ Compliant ______ Deficient</td>
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</table>

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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(b) The evaluation includes review of:

(1) The utilization of clinic [or center (N/A)] services, including at least the number of patients served and the volume of services;

491.11.b Standard  
491.11.b.1 Standard

| 1100.010.020 | ___ Compliant ______ Deficient |

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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(2) A representative sample of both active and closed clinical records; and

491.11.b.2 Standard
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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(3) The clinic's [or center's (N/A)] health care policies.

491.11.b.3 Standard

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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

491.11.c Standard
491.11.c.1 Standard
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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(2) The established policies were followed; and

491.11.c.2 Standard

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
- the areas of operation to be covered by the evaluation

The CMS regulatory text is as follows:

(3) Any changes are needed.

491.11.c.3 Standard
1100.010.050 | ___ Compliant    _____ Deficient

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
- the areas of operation to be covered by the evaluation

*The CMS regulatory text is as follows:*

(d) The clinic [or center (N/A)] staff considers the findings of the evaluation and takes corrective action if necessary.

491.11.d Standard
1600 Emergency Preparedness

1600.010 Emergency Preparedness Program

1600.010.001 Compliant _______Deficient A,B,C-M,C
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. The emergency preparedness program must include, but not be limited to, the following elements:
491.12 Condition

1600.010.002 Compliant _______Deficient A,B,C-M,C
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

1600.010.003 Compliant _______Deficient A,B,C-M,C
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

1600.010.004 Compliant _______Deficient A,B,C-M,C
The plan must include strategies for addressing emergency events identified by the risk assessment.
491.12.a.2 Standard

1600.010.005 Compliant _______Deficient A,B,C-M,C
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

1600.010.007 Compliant _______Deficient A,B,C-M,C
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
Policies and procedures. The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 1600.010.002 of this section, risk assessment in standard 1600.010.003 of this section, and the communication plan in standard 1600.010.023 of this section. The policies and procedures must be reviewed and updated at least every two (2) years.

491.12.b Standard

At a minimum, the policies and procedures must address safe evacuation from the Provider/Supplier.

491.12.b.1 Standard

Safe evacuation from the Provider/Supplier, which includes consideration of care and treatment needs of evacuees.

491.12.b.1 Standard

Safe evacuation from the Provider/Supplier, which includes staff responsibilities

491.12.b.1 Standard

Safe evacuation from the Provider/Supplier, which includes identification of evacuation locations, such as appropriate placement of exit signs

491.12.b.1 Standard

A means to shelter in place for patients, staff, and volunteers who remain in the Provider/Supplier.

491.12.b.2 Standard

A system of medical documentation that preserves patient information.

491.12.b.3 Standard

A system of medical documentation that protects confidentiality of patient information

491.12.b.3 Standard

A system of medical documentation that secures and maintains the availability of records

491.12.b.3 Standard
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.4 Standard

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

The communication plan must include names and contact information for the following: (i) Staff (ii) Entities providing services under arrangement (iii) Patients' physicians (iv) Volunteers (v) Other Provider/Suppliers within the same Medicare type

491.12.c.1 Standard

The communication plan must include contact information for the following: (i) Federal, state, tribal, regional, and local emergency preparedness staff (ii) Other sources of assistance

491.12.c.2 Standard

The communication plan must include primary and alternate means for communicating with the following: (i) Provider/Supplier's staff (ii) Federal, State, tribal, regional, and local emergency management agencies.

491.12.c.3 Standard

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.4 Standard

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.5 Standard
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 1600.010.002 of this section, risk assessment in standard 1600.010.003 of this section, policies and procedures in standard 1600.010.009 of this section, and the communication plan in standard 1600.010.023 of this section. The training and testing program must be reviewed and updated at least every two (2) years.

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.

The training program must provide emergency preparedness training at least every two (2) years.

The training program must maintain documentation of all emergency preparedness training.

The training program must demonstrate staff knowledge of emergency procedures.

If the emergency preparedness policies and procedures are significantly updated, the Provider/Supplier must conduct training on the updated policies and procedures.

Testing. The Provider/Supplier must conduct exercises to test the emergency plan at least annually.

The Provider/Supplier must participate in a fullscale 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 manmade 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.
1600.010.039 Compliant Deficient A,B,C-M,C

The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise (standard 1600.010.038) is conducted, that may include, but is not limited to the following:
A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or
B) A mock disaster drill; or
C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

1600.010.040 Compliant Deficient A,B,C-M,C

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

1600.020 Integrated Healthcare Systems

This section only applies to those providers/suppliers participating in Integrated Health Systems.

1600.020.001 Compliant Deficient A,B,C-M,C

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

1600.020.002 Compliant Deficient A,B,C-M,C

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

1600.020.003 Compliant Deficient A,B,C-M,C

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

1600.020.004 Compliant Deficient A,B,C-M,C

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
If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 1600.010.004, 1600.010.005, and 1600.010.007.

491.12.e.4 Standard

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

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

If elected, the unified and integrated emergency preparedness program must include integrated policies and procedures that meet the requirements set forth in 1600.010.009 of this section, a coordinated communication plan, and training and testing programs that meet the requirements in standards 1600.010.023 and 1600.010.031 of this section, respectively.

491.12.e.5 Standard
Please fill out the attached score sheets as part of your 2nd Year or 3rd Year Self Survey. Once completed, fill in the Facility ID and Facility name. Also, have the Director fill in his/her name, sign, and date. Note that you will be responsible for any updates to the Standards during your 2nd and 3rd Year Self Surveys.

Facility ID ________

Medical Director (print) ____________________________________

Medical Director (signature) ___________________________ Date _______
Section 100: § 491.1 Purpose and scope
100.010.005 ___Compliant ___Deficient

Section 200: § 491.2 Definitions
200.010.005 ___Compliant ___Deficient

Section 300: § 491.3 Certification procedures
300.010.005 ___Compliant ___Deficient

Section 400: § 491.4 Compliance with Federal, State and local laws
400.010.010 ___Compliant ___Deficient
400.010.015 ___Compliant ___Deficient
400.010.020 ___Compliant ___Deficient

Section 500: § 491.5 Location of clinic
500.010.010 ___Compliant ___Deficient
500.010.020 ___Compliant ___Deficient
500.010.025 ___Compliant ___Deficient
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### Section 600: § 491.6 Physical plant and environment

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### Section 700: § 491.1 Organizational structure

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### Section 800: § 491.8 Staffing and staff responsibilities

| 800.010.010 | Compliant | Deficient |
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### Section 900: § 491.9 Provision of Services

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