Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

FED - J0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition	Interpretive Guideline

FED - J0001 - CERTIFICATION PROCEDURES

Title CERTIFICATION PROCEDURES

Type Condition

CFR 491.3

Regulation Definition	Interpretive Guideline
491.3 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.	491.3 Sections 405.2401 - 405.2404 establish the procedures for certifying a clinic as an RHC and recertifying existing RHCs, including issuing a Medicare agreement, and the conditions under which an RHC's participation in the Medicare program may be terminated. Section 405.2401(b) requires compliance with the Conditions for Certification (CfC) in 42 CFR Part 491 in order for an RHC to be certified.

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FED - J0002 - CERTIFICATION PROCEDURES

Title CERTIFICATION PROCEDURES

Type Standard

CFR 491.3 & 405.2412

Regulation Definition	Interpretive Guideline
Standard-Level Tag	491.3 & § 405.2412
§ 491.3 Certification procedures A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405…. § 405.2412 Physicians' services. Physicians' services are professional services that are furnished by either of the following: (a) By a physician at the RHC . . . (b) Outside of the RHC … by a physician whose agreement with the RHC . . . provides that he or she will be paid by the RHC . . . for such services and certification and cost reporting requirements are met.	RHCs are permitted to provide their physician services outside the premises of the RHC, (i.e., a patient's home, a Part A SNF or at the scene of an accident, so long as there is a written agreement between the RHC and the physician. Note: " Services provided inside a mobile RHC unit are considered to be provided inside the RHC; and " A physician who provides RHC services is also free to provide physician services that are not RHC services outside the RHC; in this case the physician bills for those services separately rather than being reimbursed for them by the RHC. The agreement between the RHC and a physician must specifically provide that the RHC pays the physician for the RHC services provided, and that the RHC will continue to meet Medicare certification and cost reporting requirements.

FED - J0003 - CERTIFICATION PROCEDURES

Title CERTIFICATION PROCEDURES

Type Standard

CFR 491.3 & 405.2416 -2417

Regulation Definition	Interpretive Guideline
Standard-Level Tag	

Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

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 . . .

§ 405.2416 Visiting nurse services.
(a) Visiting nurse services are covered if the services meet all of the following:
(1) The RHC . . . is located in an area in which the Secretary has determined that there is a shortage of home health agencies.
(2) The services are rendered to a homebound individual.
(3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC . . .
(4) The services are furnished under a written plan of treatment that is both of the following:
(i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC . . .; or
(B)(1) Established by a nurse practitioner, physician assistant or certified nurse midwife; and
(2) Reviewed at least every 60 days by a supervising physician.
(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC . . .
(b) The nursing care covered by this section includes the following:
(1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.
(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to

exercise and to take medications.
(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.
(d) For purposes of this section, homebound means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or long term care facility.

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.
A shortage of home health agencies exists if the Secretary determines that the RHC . . .
(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC . . .
(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency.
(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.
Interpretive Guidelines § 491.3 & § 405.2416 - §2417

RHCs are permitted to offer visiting nurse services (VNS) in patients' homes if they are located in an area with a shortage of home health agencies. To provide VNS, the RHC must apply to the SA, which performs an assessment in accordance with Section 2246 of the SOM. Based on this assessment the SA makes a recommendation to the CMS RO, and the RO makes the determination whether the RHC will be permitted to offer

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VNS.

If an RHC provides VNS, the SA must confirm that the services are being provided:

o by a registered nurse (RN) or a licensed practical nurse who is employed by or receives compensation from the RHC for providing such services;

o in accordance with a written plan of treatment which is:
o established and signed by a supervising RHC physician, nurse practitioner, physician assistant, or certified nurse midwife;
o reviewed and signed at least every 60 days by the supervising RHC physician; and
o identifies the nursing and personal care services that are to be provided to the individual.

The VNS must be provided in the patient's home and must be documented in the RHC's clinical records, in accordance with the requirements at § 491.10.

FED - J0010 - COMPLIANCE WITH FED., STATE & LOCAL LAWS

Title COMPLIANCE WITH FED., STATE & LOCAL LAWS

Type Condition

CFR 491.4

Regulation Definition

491.4 Compliance with Federal, State and local laws

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

Interpretive Guideline

491.4

The RHC must ensure that it meets all applicable Federal, State and local law and regulations. Depending on the manner and degree of noncompliance with the standards contained in this Condition, condition-level noncompliance may be present and must be cited.

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FED - J0011 - COMPLIANCE WITH FED., STATE & LOCAL LAWS

Title COMPLIANCE WITH FED., STATE & LOCAL LAWS

Type Standard

CFR 491.4

Regulation Definition	Interpretive Guideline
Standard-level Tag	491.4
491.4 Compliance with Federal, State and local laws	Other Federal Requirements
The rural health clinic . . . and its staff are in compliance with applicable Federal, State and local laws and regulations.	Neither CMS, nor State surveyors conducting surveys on its behalf, has the authority to interpret and enforce the laws and regulations of other Federal agencies. Further, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies. However, a surveyor who suspects an RHC may not be in compliance with other Federal requirements may refer the matter to the appropriate agency having jurisdiction. If CMS is notified of or becomes aware of another Federal agency's final enforcement action, citations under this regulation would be appropriate, but only if the other agency's final enforcement action remains in effect and the violation of the other agency's regulations has not been corrected.

FED - J0012 - LICENSURE OF CLINIC OR CENTER

Title LICENSURE OF CLINIC OR CENTER

Type Standard

CFR 491.4(a)

Regulation Definition	Interpretive Guideline
§ 491.4(a) Licensure of clinic …	491.4(a)
The clinic or center is licensed pursuant to applicable State and local law.	State licensure requirements generally exist for healthcare facilities. States may vary in their licensure requirements for entities that meet the Medicare definition of an RHC. Some States may not require licensure of these facilities at all, or may permit them to be licensed as part of another entity. In States where a separate facility license is required for a facility seeking to participate or already participating in Medicare as an RHC, the RHC must have a current

license that has not expired or been suspended or revoked. The RHC must also be in compliance with all the State licensure requirements.

Neither CMS nor State surveyors conducting surveys on its behalf have the authority to interpret or enforce State licensure or other state laws. Failure of the RHC to meet State licensure law may be cited during the Federal survey only if the State has made a determination of noncompliance and has also taken a final enforcement action as a result. (Citation of licensure deficiencies on a State survey may represent an initial step rather than a final action or determination by the State licensure authority.) Additionally, the Federal survey of the RHC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an RHC had received a State licensure citation in the previous year would not be grounds for citing the RHC for noncompliance with State licensure law, unless the State licensure authority has taken a final action and indicates the RHC is noncompliant at the time of the survey.

If as a result of a State citation of an RHC for deficiencies in its compliance with licensure requirements, the RHC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare agreement as of the last date on which it provided services to Medicare beneficiaries in accordance with § 405.2404(a)(3), which is cross-referenced in § 491.3 of the RHC CfCs). The SA must advise the RO of the RHC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the RHC's State license has been revoked or suspended, then the RHC is not in compliance with this condition and must be cited for a condition-level deficiency. Furthermore, survey of the rest of the CfCs cannot be completed, since the RHC is not providing medical services to patients. The SA must advise the RO of such revocation or suspension, and the RO will proceed with action to terminate the RHC's Medicare agreement in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the RHC may not be in compliance with State or local licensure laws, the information may be referred to the State licensure authority for follow-up.

FED - J0013 - LICENSURE/CERT/REGISTRATION OF PERSONNEL

Title LICENSURE/CERT/REGISTRATION OF PERSONNEL

Type Standard

CFR 491.4(b)

Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

Regulation Definition	Interpretive Guideline
491.4(b) Licensure, certification or registration of personnel. Staff of the clinic . . . are licensed, certified or registered in accordance with applicable State and local laws.	491.4(b) The laws requiring licensure vary from State to State. Examples of healthcare professionals that a state may require to be licensed could include: MD/DOs, dentists, physician assistants, nurse practitioners and nurses. Examples of personnel that a state might require to be certified or registered could include dieticians, technicians who administer diagnostic imaging procedures, pharmacy technicians, laboratory technicians, etc. All RHC staff members that are required to be licensed, certified or registered by the State where the RHC is located must possess a current license, certification or registration, as applicable. It is the RHC's responsibility to ensure that all clinic personnel hold an appropriate and current license, certification or registration. There are considerable variations in the States' health care professional laws and regulations governing scope of practice acts relative to the extent to which physicians may delegate responsibilities to physician assistants, nurse practitioners and certified nurse-midwives. If a State requires a nurse practitioner or physician assistant to have all of their orders co-signed by a physician or establishes other requirements for supervision, the RHC must ensure that its staff complies. In all cases, patient care must be provided by practitioners practicing within their permitted scope of practice under State law.

FED - J0020 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

Type Condition

CFR 491.5

Regulation Definition	Interpretive Guideline
491.5 Location of clinic.	Depending on the manner and degree of noncompliance with the standards of this condition, condition-level noncompliance may be cited.

FED - J0021 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

Type Standard

CFR 491.5(a)(1), 491.5(c) and 491.5(d)

Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

Regulation Definition

491.5(a) Basic requirements.

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

491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

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.

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).

491.5(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.
(2) Excluded from the rural area classification are:
(i) Central cities of 50,000 inhabitants or more;
(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;
(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

Interpretive Guideline

491.5(a)(1), § 491.5(c) & § 491.5(d)

Only the CMS RO may make a determination as to whether an existing or prospective RHC is located in a rural area that is also designated as a shortage area. The RO relies upon information from:

o The US Census Bureau as to whether a location is in a rural area; and

o The Health Services and Resources Administration (HRSA) as to whether a location is in a designated shortage area.

See Sections 2240 - 2242 of the SOM for more information about how the RO makes determinations as to whether an RHC meets the location requirements. The SAs may conduct preliminary assessments of the eligibility of an initial applicant for certification as an RHC, in order to avoid conducting a survey of a potentially ineligible applicant. If the SA suspects an applicant's location is not eligible, it advises the RO promptly, so that the RO can make a determination. Should this situation occur, the SA should not conduct a survey of the applicant unless the RO advises that it has found the applicant's location to meet the location requirements.

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

491.5(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:
(i) The ratio of primary care physicians practicing within the area to the resident population;
(ii) The infant mortality rate;
(iii) The percent of the population 65 years of age or older; and
(iv)The percent of the population with a family income below the poverty level.
(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:
(i) The area served is a rational area for the delivery of primary medical care services;
(ii) The ratio of primary care physicians practicing within the area to the resident population; and
(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

FED - J0022 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

Type Standard

CFR 491.5(a)(3)(i) and (ii)

Regulation Definition	Interpretive Guideline
Basic requirements	Interpretative Guidelines § 491.5(a)(3)(i)-(ii)

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§ 491.5(a)(3) . . . the RHC . . . may be permanent or mobile units.

(i) Permanent unit. The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic . . . are housed in permanent structure.

(ii) 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).

An RHC may be housed in:

- a fixed, permanent structure;
- a mobile unit; or
- a permanent structure which also provides RHC services in one or more mobile units.

In all cases, each structure or unit must contain within it all the objects, equipment, and supplies required by the RHC for the clinical services that it furnishes.

Mobile Unit

An RHC that consists only of a mobile unit must comply with all of the CfCs in that unit, including the location requirements. All mobile units, regardless of whether they are the entire RHC or a part of an RHC that also has a permanent structure, must have a fixed set of locations in which the unit is scheduled to be providing services at specified dates and times, and each unit must adhere to this schedule. For new applicants, the mobile locations in which services are provided must meet the rural and shortage area requirements at the time of survey. For existing RHCs, if services are being provided at locations other than its original locations, the new locations must meet the rural and shortage area requirements at the time of survey. This does not mean that the RHC is not able to periodically change the schedule for its mobile services. Instead, it means that the mobile unit must operate at locations that meet the location requirements and those locations and times are documented by the RHC and made available to the public in advance of scheduled operations, so that patients can know when and where services will be available to them. The schedule of times and locations must be posted on the mobile unit but must also be publicized by other means that patients could consult in advance, e.g., on a website, in local libraries or stores, etc.

FED - J0023 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

Type Standard

CFR 491.5(a)(3)(iii)

Regulation Definition

Basic requirements

491.5(a)(3) . . . the RHC . . . may be permanent or mobile units.

Interpretive Guideline

491.5(a)(3)(iii)

A Medicare-certified RHC is not permitted to have more than one permanent unit, i.e., it may not operate out of permanent structures in more than one location. Location is identified as the physical address where medical services

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(iii) Permanent unit in more than one location. If clinic . . . services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic . . .

are provided. If an organization owns several facilities operating out of permanent units at different locations; that it seeks to enroll in Medicare in order to provide RHC services in each facility, it must enroll each permanent unit separately, and each must independently and fully comply with the RHC CfCs. If one RHC occupies several suites within the same building, sharing the same address, it is considered to have only one permanent unit. It is also possible for separate RHCs to occupy different suites in the same building; when this occurs, each RHC must independently meet the RHC CfCs, and cannot co-mingle their services.

FED - J0024 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

Type Standard

CFR 491.5(b)(1), (b)(2) and (b)(3)

Regulation Definition

491.5(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.

(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.

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

Interpretive Guideline

491.5(b)(1) - § 491.5(b)(3)

Loss of Location Eligibility

A provider or supplier is expected to be in substantial compliance with its applicable conditions at all times. This applies to conditions which establish facility location requirements as well. But for RHCs, there is a grandfathering provision which applies to an existing certified RHC and its existing location that permits the RHC to remain an RHC even if population growth and/or changes in the availability of health care practitioners results in their no longer meeting the location requirements at § 491.5(a)(1).

CMS makes a presumption that every RHC seeks continued certification for participation in Medicare, including by application of this exception when necessary, unless the RHC has notified CMS of a voluntary termination of its RHC agreement. As a result, there is no special procedure for the RHC to file a request for exception to the location requirements and there is no new determination by the CMS RO concerning a certified RHC's ongoing compliance with the location requirements when the SA conducts a full RHC survey, regardless of whether the survey is conducted for periodic recertification of the RHC, as a representative sample validation survey, or for any other purpose. Although the grandfathering provision means that CMS does not terminate a certified RHC's Medicare agreement due to its location no longer meeting the rural or shortage area location requirements, CMS does continue to collect RHC location data. SAs conducting full surveys must still collect this and other data specified on the Form CMS-29, Verification of Clinic Data - Rural Health Clinic Program. The information collected is updated in the Automated Survey Process Environment (ASPEN) which may be aggregated and used for future policy analysis.

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Relocation

The grandfather provision applies to existing RHCs and the existing location of the RHC. If an existing RHC relocates, the grandfathering provision no longer applies to that RHC and their new location. The RHC must meet both the rural and shortage area location requirements at the new location. The CMS RO is responsible for making the actual determination of compliance with the location requirements for the new location. As with initial RHC location determinations, CMS ROs do not provide advance/preliminary determinations on the location eligibility of a potential relocation site. Determinations are made only after the RHC relocation has occurred, and the CMS-855A has been submitted by the RHC to the appropriate Medicare Administrative Contractor, and the Form CMS -29 has been submitted by the RHC to the SA.

In making a location determination, the ROs rely upon the following public tools:

o the Census Bureau's American FactFinder tool, http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml, when making rural area determinations; and
o HRSA information, primarily through HRSA's Data Warehouse, http://www.hrsa.gov/shortage/find.html, when making shortage area determinations.

RHCs contemplating a relocation are free to independently utilize the Census Bureau's American Factfinder and HRSA's Data Warehouse to assist with their planning, but CMS will not make a final determination until the relocation has taken place. For detailed instructions on how to utilize these tools, see S&C 13-30-RHC for rural area and S&C 15-09 for shortage area determinations. Sections 2240 - 2242 of the SOM provides additional information regarding how the RO determines the status of an RHC.

Although an onsite survey is not required, the CMS RO has the discretion to require a survey in individual cases to verify that services are being provided at the new location identified in the submitted documentation.

Facilities Operating on July 1, 1977

This provision applies to initial applicants for RHC certification and therefore is not likely to have any practical application at this time. The SA should consult with the CMS RO if it believes it has encountered a situation where this provision would apply.

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FED - J0040 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Condition

CFR 491.6

Regulation Definition	Interpretive Guideline
491.6 Physical plant and environment.	Depending on the manner and degree of noncompliance with the standards within this condition, there may be condition-level noncompliance.

FED - J0041 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Standard

CFR 491.6(a)

Regulation Definition	Interpretive Guideline
491.6(a) Construction: The clinic and the center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.	Interpretative Guidelines 491.6(a) The RHC must ensure that the physical plant of its permanent and/or mobile unit is constructed, arranged in terms of its layout, and maintained in a manner to ensure patient access and safety of its patients and personnel. The clinic's layout and fixtures must not present hazards that increase risk of patient injury, such as slippery floors or torn carpets that may present tripping or fall hazards, or ceilings panels that are in danger of falling, etc. The physical plant also must be designed and constructed in accordance with applicable State and local building, fire, and safety codes, but surveyors conducting RHC surveys on behalf of CMS do not assess compliance with such State and local code requirements. Further, the clinic must have enough space, for the fixtures, equipment and supplies required, in order for it to provide those RHC services which must be furnished directly, i.e., provided within the RHC rather than under arrangement. The clinic must also comply with applicable Federal, State and local laws and regulations and accepted standards of practice for primary care services when determining how much space it requires for its direct services.

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FED - J0042 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Standard

CFR 491.6(b) and (b)(1)

Regulation Definition	Interpretive Guideline
491.6(b) Maintenance: The clinic . . . 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)) The RHC must have a preventive maintenance program which ensures all essential mechanical, electrical and patient-care equipment is maintained so that it operates safely. Essential mechanical, electrical and patient care equipment includes things such as heating, ventilation and air conditioning systems, electrical systems, plumbing systems, telephone systems, elevators, and any biomedical equipment the clinic uses. Biomedical equipment means devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the clinic, e.g., blood pressure monitors, re-usable diagnostic scopes, EKG machines, scales, laboratory equipment, etc. All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades. All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using qualified clinic personnel, contracted services, or through a combination of clinic personnel and contracted services. For example, clinics that rent space in buildings with other occupants generally would have a contractual agreement with the landlord for maintenance of essential building systems. Clinics may also contract for maintenance of their biomedical equipment. In all cases, clinics must follow or ensure that their contractors follow equipment manufacturers' recommended maintenance activities and schedules. Clinics must document their preventive maintenance activities. This documentation must be incorporated into the RHC's program evaluation plan.

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FED - J0043 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Standard

CFR 491.6(b)(2)

Regulation Definition	Interpretive Guideline
The clinic . . . has a preventive maintenance program to ensure that: 491.6(b)(2) Drugs and biologicals are appropriately stored; and	Interpretative Guidelines 491.6(b)(2) The RHC must ensure the appropriate storage of drugs and biologicals which are used in the clinic. Drugs and biologicals must be stored and maintained in accordance with the manufacturer's instructions for temperature and other environmental conditions as well as expiration dates, etc. They may not be stored in areas that are readily accessible to unauthorized individuals/personnel. The clinic's policies and procedures must identify which types of clinic staff are authorized access to drugs and biologicals. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are considered secure. If medications are kept in cabinets located in areas where patients, visitors or other unauthorized personnel have ready access when clinic personnel are not also present, the cabinets must be locked.

FED - J0044 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Standard

CFR 491.6(b)(3)

Regulation Definition	Interpretive Guideline
The clinic . . . has a preventive maintenance program to ensure that: 491.6(b)(3) The premises are clean and orderly.	Interpretative Guidelines 491.6(b)(3) The RHC must provide and maintain a clean and orderly environment. All areas of the clinic must be clean. These areas include, but are not limited to, the waiting area(s), exam room(s), staff lunch room(s), rest room(s), and office space. The clinic must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and clean environment. Policies and procedures for

Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

an orderly and clean environment must address the following:

- Measures taken to maintain a clean and orderly environment during internal or external construction/renovation;
- Measures to prevent the spread of infectious diseases. At a minimum the following must be addressed:
- Hand hygiene for staff having direct patient contact;
- Safe injection practices;
- Single-use devices, and, when applicable, high-level disinfection and sterilization;
- Safe use of point-of-care devices;
- Routine cleaning of environmental surfaces, carpeting, and furniture;
- Disposal of waste, including medical waste;
- Food sanitation, if employee food storage and eating areas are provided; and
- Pest control.

FED - J0060 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

Type Condition

CFR 491.7

Regulation Definition	Interpretive Guideline
491.7 Organizational structure.	Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance

FED - J0061 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

Type Standard

CFR 491.7(a)(1) and (b)(3)

Regulation Definition	Interpretive Guideline
491.7(a) Basic requirements.	491.7(a)(1) & 491.7(b)(3)
(1) The clinic . . . is under the medical direction of a	The clinic must be under the medical direction of a physician who is responsible for the quality and appropriateness

physician, and has a health care staff that meets the requirements of § 491.8.

(b) Disclosure. The clinic . . . discloses the names and addresses of: . . .

(3) The person responsible for medical direction.

491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and
(2) 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 Act for specific limitations).

of health care services furnished in the RHC. In light of the definition of a physician at § 491.2 and due to the supervisory and oversight responsibilities involved in providing medical direction, only an MD or DO may serve as the RHC's medical director. The MD or DO must hold a current license that is issued or recognized by the State in which the RHC is located. The nature of medical director's duties are specified at § 491.8(b). By contrast, the language of § 491.7(a)(1) is focused on the requirement for the RHC to have an individual who is explicitly charged with being the clinic's medical director. There must be documentation available in the RHC identifying the name, address, and phone number of the clinic's medical director.

Any change in the physician responsible for the clinic's medical direction requires immediate notification to the appropriate SA. When identifying a new physician responsible for medical direction, the RHC provides the SA with the name, address, and phone number of the new medical director and evidence that the physician is licensed to practice in the State in which the RHC is located. Such change in medical director does not require resurvey or recertification, if the change can otherwise be adequately verified.

There is no waiver available should the physician functioning as the medical director leave a clinic that is already certified as an RHC. However, CMS affords currently certified RHCs a reasonable time to come back into compliance with the physician medical director requirement if the RHC can provide documentation that it initiated good faith efforts prior to the survey to obtain the regular services of a physician medical director, as well as arrangements it has made for immediate temporary physician services to perform required physician responsibilities in accordance with § 491.8(b). This flexibility is not available to an applicant for initial RHC certification.

In this situation, the already-certified RHC must still be cited for violating § 491.7(a)(1), but there is discretion with respect to the length of time the RHC is allowed to implement a plan of correction. Since the RHC regulations permit the RHC physician medical director to carry out many of his/her responsibilities via telecommunications and to provide telemedicine services, generally an RHC should be able to secure the required physician services within a reasonable period of time. The SA must make a recommendation to the CMS RO on whether to provide an RHC an extended period of time to implement a PoC. The RHC must inform the SA of all actions taken to recruit a replacement and expected outcome.

NOTE: To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.

The clinic must also have a health care staff that meets the requirements of § 491.8. This portion of this standard is evaluated under § 491.8, but deficiencies cited under that provision may also be cited under § 491.7(a)(1)

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FED - J0062 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

Type Standard

CFR 491.7(a)(2) and (b)(1)-(2)

Regulation Definition

491.7(a) Basic requirements.

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

(b) Disclosure. The clinic . . . 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);

(2) The person principally responsible for directing the operations of the clinic . . .

Interpretive Guideline

491.7(a)(2) and 491.7(b)(1)-(2)

The clinic must establish in writing the manner in which it is organized, including the person who is principally responsible for the day-to-day operations, the lines of authority between that individual and the owner(s) and between that individual and other staff of the RHC. The RHC must identify in writing all types of staff positions, their place in the organizational arrangement, and their functions and responsibilities. There must be a written record of the name and address of the person who is principally responsible for the day-to-day operations of the clinic and this information must be furnished to surveyors upon request.

With respect to the requirement for disclosure of the clinic's owners, the latest disclosure should be contained in the latest copy of the Form CMS-855A, Medicare Enrollment for Institutional Providers, which the clinic is required to file in order to enroll in the Medicare program and required to update if its information changes. The MAC provides the CMS RO and SA copies of updates to the Form CMS- 855A information it receives. Review of this information disclosure is handled primarily by the MAC. It is the responsibility of the RHC to file an updated Form CMS 855 A with the MAC if there are changes to the information it previously submitted.

The Form CMS-29, Verification of Clinic Data - Rural Health Clinic Program, which is used to collect clinic ownership information and clinic personnel data, is also completed. See Chapter 2 of the SOM, section 2200 for detailed instructions on completing the CMS-29.

The clinic must have written policies and procedures addressing both administrative and clinical activities. Requirements for patient care policies are specified at §491.9(b) and are not evaluated under § 491.7(a)(2). Administrative policies and procedures would address topics such as personnel, fiscal, purchasing, and building and equipment maintenance, as well as any other topics the clinic's management finds pertinent.

Aspen Federal Regulation Set: J 10.00 RURAL HEALTH CLINIC

FED - J0080 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Condition

CFR 491.8

Regulation Definition	Interpretive Guideline
491.8 Staffing and Staff Responsibilities.	Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance.

FED - J0081 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(1) and (2)

Regulation Definition	Interpretive Guideline
491.8(a) Staffing. (1) The clinic . . . has a health care staff that includes one or more physicians . . . (2) 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 this section.	491.8(a)(1) and (2) An RHC must, at a minimum, have a health care staff that includes one or more physicians; if the clinic has only one physician, that physician must be either an MD or a DO in order to perform the responsibilities of the clinic's medical director. The physician must hold a current license issued or recognized by the State in which the RHC is located. The physician(s) may be the clinic's owner (who may also be an employee of the clinic at the same time), an employee of the clinic, or providing services to the clinic under a contractual arrangement. CMS interprets an "employee" to be an individual to whom the clinic issues an IRS Form W2, Tax and Wage Statement (See 79 FR 25462, May 2, 2014). If the physician is not responsible for medical supervision nor the medical direction of the clinic, contractual arrangements may either be directly between the clinic and an individual physician, or between the clinic and a third-party entity that supplies the clinic with physician services, such as a locum tenens agency. In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

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FED - J0082 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(1) and (3)

Regulation Definition

491.8(a) Staffing

(1) . . . Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(3) The physician assistant, nurse practitioner, . . . may be the owner or an employee of the clinic . . ., or may furnish services under contract to the clinic . . . In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

Interpretive Guideline

491.8(a)(1) and (3)

In addition to having a physician on staff, the RHC's health care staff must also include one or more nurse practitioner(s) (NP) or physician assistant(s) (PA), as defined at § 491.2. The RHC's NP and/or PA must meet the Medicare definition of an NP or PA and be licensed in accordance with the law of the State in which the RHC is located and practicing within their permitted State scope of practice.

At least one NP or PA must be an employee of the RHC (note that a clinic's owner may also be an employee; this is at the owner's discretion). CMS interprets an "employee" to mean an individual to whom the clinic issues an IRS Form W-2, Wage and Tax Statement. (See 79 FR 25462, May 2, 2014) However, once the clinic has employed at least one NP or PA, the other practitioners may furnish services under contract to the clinic instead of being employees. These other NPs or PAs may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

o As provided by § 1861(aa)(7) of the Act, and implemented in Section 2248 of the SOM, an existing RHC may request a waiver of the requirement to employ a NP or PA. The mid-level staffing waiver is applicable to Medicare-participating RHCs only. Initial applicants to participate in Medicare as an RHC are not eligible for staffing waivers. CMS grants a currently certified RHC a one-year waiver of the requirement to employ a NP or PA if:

o The RHC submits the written request for a waiver to the appropriate SA;

o The RHC demonstrates that it has been unable, despite reasonable efforts, to hire a NP or PA in the previous 90-day period; and

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o The RHC's request is submitted six months or more after the date of the expiration of any previous such waiver for the RHC.

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire an NP or PA in the previous 90 days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

FED - J0083 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(3)

Regulation Definition	Interpretive Guideline
491.8(a) Staffing. (3) The . . . nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic . . .	491.8(a)(3) The clinic is not required to have a nurse-midwife, clinical social worker or clinical psychologist on staff. If it does have any of these on staff, they must be licensed as required by State law of the State in which the clinic is located, and must be practicing within their permitted scope of practice. A nurse midwife, clinical social worker or clinical psychologist who is on the clinic's staff may be the clinic's owner (who may also be an employee at the same time), an employee of the clinic, or providing services to the clinic under a contractual agreement. These types of practitioners may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

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FED - J0084 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(4)

Regulation Definition	Interpretive Guideline
491.8(a) Staffing. (4) The staff may also include ancillary personnel who are supervised by the professional staff.	491.8(a)(4) The clinic's staff may include personnel who are not practitioners but who provide clinical services, for example, registered nurses, licensed practical nurses, laboratory technicians, etc. In all cases personnel must hold current State licenses when required. All such personnel must be supervised at all times by a practitioner, either a physician or a non-physician practitioner, on the RHC's professional healthcare staff. Supervisory responsibilities may be shared among practitioners. For example, an NP on the RHC's staff may be the official supervisor who conducts regular performance reviews, but when that NP is not on duty, the RHC's physician or another NP or other non-physician practitioner may provide supervision.

FED - J0085 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(5) and (6)

Regulation Definition	Interpretive Guideline
491.8(a) Staffing. (5) The staff is sufficient to provide the services essential to the operation of the clinic . . . (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	491.8(a)(5) & (6) The clinic must be sufficiently staffed to provide the services offered by the RHC. Specifically, this means that the clinic has sufficient staff practicing within their permitted scope of practice to provide RHC services to the clinic's patients at all hours that the clinic is open and operating. Consistent with § 491.9(c), the RHC services the clinic furnishes are diagnostic and therapeutic services and supplies similar to those furnished in a physician office, including, but not limited to, performing history and physical examinations, assessment of health status, and treatment for a variety of medical conditions. The clinic must also furnish specified laboratory services and first responder-type

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times the clinic . . . operates. . . .

emergency services to individuals in the clinic experiencing a medical emergency. The clinic must have sufficient staff members who are qualified to furnish these services to the volume of patients the RHC sees. Even when staffing meets the minimum requirement in terms of practitioner time at the RHC, the staffing may be insufficient for the volume of services the RHC provides.

The clinic may only be open and furnishing RHC services if there is a physician, NP, PA, certified nurse midwife, clinical social worker, or clinical psychologist on site and available to furnish services. Although the physician medical director may perform many, not all, of his/her responsibilities remotely via telecommuications, this does not mean the clinic can be open and furnishing services without any practitioner on-site. With the exception of services the clinic's medical director or other MDs or DOs may provide by telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioners who are on site at the time the services are offered. The loss of a PA or NP staff member may require the RHC to request a temporary staffing waiver via its SA. It may also require a temporary adjustment of the clinic's operating hours or services and an adjustment in visits by the physician(s) providing medical direction. It is the responsibility of the clinic to promptly advise the SA of any changes in staffing which would affect its certification status.

(NOTE: See the guidance for § 491.8(a)(3) and Section 2248 for more details on the waiver process and the expectations for RHCs and SAs.)

RHCs may allow beneficiary entry to the waiting room or other non-patient care areas to handle billing inquiries or to get out of the weather when the mid-level practitioner as defined in §493.2, clinical social worker, clinical psychologist or physician staff member is not present to provide health care services. However, the clinic is not considered to be in operation as an RHC during this period. No health care services may be provided until a mid-level practitioner, clinical social worker, clinical psychologist or physician staff member is present onsite. There should be a reasonable timeframe between administrative transactions conducted on the premises outside the hours of operation of the RHC and the commencement of RHC operations with the healthcare professional's arrival. Any RHC that choose to exercise this flexibility should post the hours of administrative services only versus the hours of RHC operations. Signage should clearly delineate times the healthcare professional staff member is present onsite. If State law does not allow access to the RHC premises when the clinic is not in operation as an RHC, the facility must adhere to such laws.

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FED - J0086 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(a)(6)

Regulation Definition

491.8(a) Staffing.

(6) . . . for RHCs, a nurse practitioner, physician assistant or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

Interpretive Guideline

491.8(a)(6)

A NP, PA or certified nurse-midwife (CNM) must be available to furnish patient care services at least 50 percent of the operating hours during which RHC services are offered, even when a physician is also present in the clinic. All time that a NP, PA or certified nurse-midwife (CNM) is present in the clinic during the clinic's operating hours, even if not actually providing RHC services to patients, may be counted toward the 50 percent requirement. In addition, when RHC services are furnished to clinic patients outside of the clinic (e.g. in the patient's home, in a SNF, or in another residential facility), the time spent providing RHC services outside the clinic (excluding travel time) may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a NP, PA, CNM, CSW nor a CP is available on-site, a physician must be available on-site to provide needed services in order for the RHC to be open and operating. With the exception of services the clinic's medical director or other MDs or DOs may provide via telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioner(s) who are on site at the time the services are offered".

The following are some examples of how determinations regarding the 50 percent requirement may be made:

A clinic offers RHC services from 10 a.m. to 5 p.m. Tuesday through Friday, for a total of 28 hours per week. A physician, NP, PA, CNM, clinical social worker, or clinical psychologist must be available to furnish patient care services, within their permitted scope of practice, during all 28 service hours. In addition, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence for at least 14 hours (50 percent of the 28 service hours) for the RHC to furnish patient care services.

Note: If the NP, PA or CNM are not providing RHC services on-site, the physician must be available on-site.

In some cases, the clinic's weekly schedule may not be a reasonable period of time on which to base these

determinations, and consideration of a biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when the clinic's schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 a.m. to 4 p.m., and one Friday a month from 10 a.m. to 4 p.m., for a total of 18 hours per month. Of these 18 hours, a NP, PA, or CNM must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 50 percent of that time (9 hours) for the RHC to furnish patient care services. This requirement would be met if a NP, PA, or CNM was on-site on one Tuesday for 3 hours and on the Friday for 6 hours, or through some other schedule that results in their availability 9 hours/month.

As provided by § 1861(aa)(7)(A) of the Act, and implemented in Section 2248 of the SOM, RHCs may request a waiver of the requirement that a NP, PA or CNM be available to furnish patient care services at least 50 percent of the time the RHC operates. The waiver is applicable to Medicare-participating RHCs only. Initial applicants requesting to participate in Medicare as an RHC are not eligible for mid-level staffing waivers. CMS grants a currently certified RHC a one-year waiver of the NP/PA/CNM staffing requirement if:

o The RHC submits to the SA a written request for a waiver;

o The RHC demonstrates that it has been unable, despite reasonable efforts, to arrange to have either a NP, PA, or CNM on duty at least 50 percent of the time the RHC operates in the previous 90-day period.

o The RHC's request is submitted 6 months or more after the date of the expiration of any previous such waiver for the RHC.

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire a NP, PA or CNM in the previous 90 calendar days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

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FED - J0100 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(b)(1) and (3)

Regulation Definition

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

(1) . . . provides medical direction for the clinic's . . . health care activities and consultation for, and medical supervision of, the health care staff.

(3) . . . provides medical orders, and provides medical care services to the patients of the clinic or center.

Interpretive Guideline

491.8(b)(1) & (3)

In accordance with § 491.8(b), the MD or DO physician who serves as the RHC's medical director in accordance with § 491.7(a)(1) is responsible for the overall medical direction of the clinic's clinical activities. He or she also provides clinical consultation to and supervises the other physician(s) as well as the non-physician practitioners on the RHC's health care staff. This requirement for "supervision" does not limit the ability of non-physician practitioners to practice in accordance with their State scope of practice. For example, if State law permits an NP to practice independently when providing diagnosis and treatment, including writing orders and prescriptions, the NP would be permitted to do so in the RHC as well. However, the NP, like any other member of the clinic's staff of health care practitioners, would be under the overall medical supervision of the clinic's medical director, who is responsible for the quality of care in the clinic.

In addition to medical direction as described above, the physician must provide assessment, diagnosis, and treatment of patients, and provide medical orders for patients in need of diagnostic tests and/or therapeutic treatments.

If the clinic has more than one physician on its staff, the other physician(s) may also provide medical services, medical orders, and consultation, but only one physician, who must be an MD or DO, can serve as the clinic's medical director and provide overall direction to its clinical activities.

NOTE: To ensure continuity of care, it is permissible to use a locum tenens (i.e., temporary) MD/DO as the medical director of the RHC, providing that same MD/DO is contractually bound to provide services to the clinic for a minimum of six months.

A physician is not required to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no other physician, NP, CNM, PA, clinical social worker or clinical psychologist is

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present in the RHC. With the development of technology that facilitates telemedicine, a physician has the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, clinical record review, including being on-site at the facility to provide medical care services to patients. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate based on the needs of the clinic, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician on-site presence that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

FED - J0101 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(b)(3) and (c)(1)(ii)

Regulation Definition	Interpretive Guideline
491.8(b) Physician responsibilities. The physician performs the following: (3) Periodically reviews the clinic's . . . patient records . . . 491.8(c) Physician assistant and nurse practitioner responsibilities. (1) The physician assistant and the nurse practitioner members of the clinic's . . . . staff: (ii) Participate with a physician in a periodic review of the patients' health records.	491.8(b)(3) & (c)(1)(ii) A physician must review periodically the RHC's patient clinical records. In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, an RHC physician must review and sign all such records. If there is more than one physician on the RHC's staff, it is permissible for staff physicians other than/in addition to the medical director to review and co-sign the records. The RHC's NP(s) and/or PA(s) must participate in the physician's review of the clinical records. Participation may be face-to-face or via telecommunications. If there is more than one NP or PA in the clinic, the NP or PA would participate only in the review of records of those patients for which the NP or PA provided care. Where co-signature is not required, the regulation still requires periodic physician review of the clinical records of patients cared for by non-physician practitioners. If the RHC has more than one physician on its staff, it is permissible for physicians other than/in addition to the medical director to conduct the periodic review of clinical records, so that this task might be divided or shared among the physicians. If the RHC has more than one physician, its policies and procedures must specify who is authorized (i.e. whether it is the medical director alone, or may include other staff physicians) to review and, if required under State law, co-sign clinical records of patients cared for by a non-physician practitioner.

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The regulation does not specify a particular timeframe to satisfy the requirement for "periodic" review of clinical records, but the RHC must specify a maximum interval between record reviews in its policies and procedures. The RHC is expected to take into account the volume and types of services it offers in developing its policy. For example, an RHC that has office hours only one day per week would likely establish a different requirement for record review than an RHC that is open 6 days per week/ 10 hours per day. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the RHC has electronic clinical records that can be accessed and digitally signed remotely by the physician, this method of review is acceptable. Therefore, RHCs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

FED - J0102 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(c)(2)

Regulation Definition	Interpretive Guideline
491.8(c)(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 . . . policies; (ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic . . . .; and (iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.	491.8(c)(2) The NP or PA must perform the following functions if they are not being performed by a physician: o Providing health care services in accordance with the RHC's written policies. However, non-physician practitioners must also operate within their State-permitted scope of practice and may not provide clinic services that require a broader scope of practice; o Arranging for or referring patients to services which cannot be provided at the RHC; and o Ensuring that adequate patient health records are maintained. If a patient is referred for additional treatment elsewhere, the NP or PA must ensure that the records are transferred.

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FED - J0120 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Condition

CFR 491.9

Regulation Definition	Interpretive Guideline
491.9 Provision of services.	Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

FED - J0121 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(a)(1)

Regulation Definition	Interpretive Guideline
491.9(a) Basic requirements:	Interpretative Guidelines § 491.9(a)(1)
(1) All services offered by the clinic . . . are furnished in accordance with applicable Federal, State, and local laws; and	The regulation at § 491.4 also requires compliance with applicable Federal, State and local laws. Accordingly, the guidance and survey procedures for that regulation also apply to § 491.9(a)(1).

FED - J0122 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(a)(2) and (c)(1)

Regulation Definition	Interpretive Guideline
491.9(a) Basic requirements:	Interpretative Guidelines 491.9(a)(2) & (c)(1)

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(2) The clinic . . . is primarily engaged in providing outpatient health services and meets all other conditions of the subpart. (c) Direct services - (1) General. The clinic…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

491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Direct services mean services provided by the clinic's staff.

An RHC is required to be primarily engaged in providing outpatient or ambulatory health care services. In accordance with §§ 405.2411 - 2416, RHC services include the services of physicians, NPs, PAs, certified nurse midwives, clinical psychologists and clinical social workers, along with the services and supplies that are incident to these practitioners' services. In accordance with § 491.9(c)(1), the services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system. These services include taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs and family planning.

Further, some RHCs may provide VNS if a request is submitted to the SA and approved by the CMS RO.

RHCs are not prohibited from furnishing other services, for example, ambulatory surgical procedures or diagnostic imaging services. However, they may not be primarily engaged in providing such specialized services. In the context of an RHC, "primarily engaged" is determined by considering the total hours of an RHC's operation, and whether a majority, i.e., more than 50 percent, of those hours involve provision of RHC services.

An example of a clinic schedule that combines RHC with other services would be a clinic that provides RHC services 9 a.m. to 4 p.m. Monday through Friday, and also offers diagnostic imaging services Tuesday and Friday afternoons from 1 p.m. to 4 p.m. The RHC is furnishing 35 hours of standard RHC services and 6 hours of imaging services, for a total of 41 hours of service. In this example, the RHC provides RHC services 85 percent of the time; therefore, it is "primarily engaged" in providing RHC services.

For clinics with a limited schedule, it may be more appropriate to consider the monthly total operating schedule verses the weekly schedule.

FED - J0123 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Standard

CFR 491.8(b)(2), 491.8(c)(1)(i), and 491.9(b)(1), (2), (4)

Regulation Definition

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

Interpretive Guideline

Interpretative Guidelines 491.8(b)(2) & (c)(1)(i), 491.9(b)(1), (2) & (4)

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

491.8(c) Physician assistant and nurse practitioner responsibilities.

(1) The physician assistant and the nurse practitioner members of the clinic's . . . staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic . . . furnishes;

§ 491.9(b) Patient care policies . . .

(1) The clinic's … health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(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 . . . staff.

(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...

The clinic must have written policies governing the clinical services provided. At least one RHC physician and one RHC PA or NP must participate in the development of the clinic's written policies and providing advice to the RHC's management on appropriate clinical policies. In addition, there must be at least one physician, NP, or PA who is not on the RHC's staff who participates in the development of the clinical policies. The clinic must identify in writing the names of all individuals involved in developing clinical policies. The clinical practitioners who participate in the policy development provide advice to the RHC's leadership. The RHC's leadership is not required to accept this advice, but if it exercises its authority to reject or modify the patient care policy advice of the practitioners it must be able to ensure that any changes it makes are clinically appropriate and supportable.

The clinic's patient care policies must be reviewed at least biennially or more frequently when appropriate, by a group that also contains at least one RHC physician, one RHC NP or PA, and one outside healthcare practitioner.

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FED - J0124 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(b)(3)(i) and (ii)

Regulation Definition	Interpretive Guideline
491.9(b) Patient care policies. (3) The policies include: (i) A description of the services the clinic . . . furnishes directly and those furnished through agreement or arrangement. (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 . . .	491.9(b)(3)(i) & (ii) The written RHC patient care policies must include: Description of Services The written policies must provide a description of the services the RHC furnishes, whether directly using RHC staff or through an agreement or arrangement. The services furnished by the clinic must be described in sufficient detail to permit understanding of the scope of all services furnished in the RHC, and the scope/type of agreement or arrangement they are furnished through if applicable. An example of services under arrangement might be provision by a contractor of additional laboratory services beyond those required to be performed by RHC staff. Such statements as the following may sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning. Statements such as "complete management of common acute and chronic health problems" standing alone, would not sufficiently describe services. Guidelines for Medical Management The clinic's written guidelines for the medical management of health problems include a description of the scope of medical care that may be furnished by a PA, NP, or CNM, including the extent and nature of required supervision. The guidelines would also include standard protocols for diagnosis and treatment of common conditions or for provision of preventive care. Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies. The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which

such topics as the following are discussed: The definition of the condition; its etiology; its clinical features; recommended laboratory studies; differential diagnosis, treatment procedures, complications, consultation/referral required; and follow-up. Guidelines also may be based on guidelines of nationally recognized professional organizations, which are referenced and reproduced, such as the immunization guidelines developed by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. However, the guidelines must include information on actions non-physician practitioners in the RHC are permitted to take, as well as circumstances warranting referral.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must:

o Be comprehensive enough to cover most health issues covered in a primary and preventive care setting;

o Describe the actions a NP, PA or CNM may initiate or implement, consistent with State scope of practice requirements; and

o Describe the circumstances that require consultation with the RHC's MD or DO, as well as external referral.

Guidelines may be in electronic or paper format, but should be readily accessible to RHC practitioners, all of whom must be familiar with them.

FED - J0125 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(b)(3)(iii)

Regulation Definition	Interpretive Guideline
491.9(b) Patient care policies. (3) The policies include: (iii) Rules for the storage, handling, and administration of drugs and biologicals.	Interpretive Guidelines § 491.9(b)(3)(iii) The RHC's written patient care policies must address storage, handling, and administration of drugs and biologicals within the RHC. The policies must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (USP)

(www.usp.org); the American Society of Health-System Pharmacists (http://www.ashp.org/); the Institute for Safe Medication Practices (http://www.ismp.org/default.asp); the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (http://www.ihi.org/ihi); and the Infusion Nurses Society (http://www.ins1.org).

The RHC's policies must address the following:

Storage of drugs and biologicals

Consistent with accepted professional principles, RHC's must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

Proper environmental conditions

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the RHC is expected to follow the labelled conditions. RHC's must exercise caution in administering any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

Security

The RHC must have policies and procedures that are consistent with State and Federal law to address how drugs and biologicals are stored and secured, including who is authorized access to the drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

RHCs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff members are actively providing care to patients or preparing to receive patients, i.e. setting up for injections, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked, in accordance with state and Federal law.

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If the RHC uses cart(s) containing drugs or biologicals, whenever the cart is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be within close eyesight of and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and RHC policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Record keeping for the receipt and disposition of all scheduled drugs.

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five "schedules," ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

The RHC is required to accurately track the receipt and disposition of all scheduled drugs used in the RHC. Components of a record system for scheduled drugs would include:

o Locked storage of scheduled drugs when not in use;

o Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;

o Tracking movement of all scheduled drugs from the point of entry into the RHC to the point of departure either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

o Prompt reconciliation of any discrepancies in count. The RHC is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

Handling drugs and biologicals.

"Handling" includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug's manufacturer.

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Compounding
"Handling" also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

Generally, RHCs are not settings that use compounded sterile preparations (CSPs) nor are CSPs typically furnished as part of the RHC's services. However, some RHCs may provide additional services beyond RHC services and these might include use of CSPs. If an RHC uses CSPs, it is responsible to ensure that compounding is performed consistent with accepted professional principles.

Generally, even if an RHC uses CSPs, it would not be likely to have its own pharmacy that could meet the standards of practice for preparation of CSPs; it is more likely that an RHC that uses CSPs would be acquiring them from an external source. The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an "outsourcing facility." The law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

o Must comply with the FDA's Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA's publishes the most current versions of its draft and final regulations and guidance related to compounding on its website:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm;

o Will be inspected by FDA according to a risk-based schedule; and

o Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that,"[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring

compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling."

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm

Note that these registered outsourcing facilities are also popularly referred to as "503B pharmacies."

Use of Compounding Pharmacies

If an RHC uses compounded medications and obtains them from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the RHC must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

o Ensuring that the RHC has access to quality assurance data verifying that the vendor is adhering to standards of practice for compounding medications, and can the RHC document that it obtains and reviews such data?

o Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

Note that these types of compounding pharmacies are also popularly referred to as "503A pharmacies" and generally are subject to oversight only by their State pharmacy board.

Expiration & Beyond Use Dates

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

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A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

Basic safe practices for medication administration within the RHC

The RHC's patient care policies must reflect accepted standards of practice that require the following information be confirmed prior to each administration of medication that takes place in the RHC (such as administration of vaccines or medications via injection):

o Right patient: ensuring the patient's identity. Acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the RHC; or date of birth. Identifiers must be confirmed by patient identification card, patient statement (when possible), or other means outlined in the RHC's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.

o Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;

o Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);

o Right route: the correct route, to ensure that the method of administration - orally, intramuscular, intravenous, etc. - is the appropriate one for that particular medication and patient; and

o Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the "5 rights" focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even

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when there is strict adherence to the "5 rights" of medication administration, for example when there has been a prescribing or a dispensing error.

RHCs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

FED - J0135 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(a)(3) and 491.9(c)(2)

Regulation Definition

491.9(a) Basic requirements:

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, . . .

491.9(c) Direct services

(2) Laboratory. These requirements apply to RHCs . . . . 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:
(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);
(ii) Hemoglobin or hematocrit;
(iii) Blood glucose;
(iv) Examination of stool specimens for occult blood;
(v) Pregnancy tests; and
(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guideline

491.9(a)(3) & (c)(2)

Basic laboratory services must be provided in the RHC by RHC staff in order to facilitate the immediate diagnosis and treatment of the patient. To the extent permitted under State and local law, the 6 basic laboratory services listed in § 491(c)(2) are considered the minimum laboratory services the RHC must have available within the clinic, provided by RHC staff. If any of these laboratory services cannot be provided at the RHC due to a State or local law prohibition, that laboratory service is not required for Medicare certification. These laboratory services must be provided in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR Part 493 operating under a current CLIA certificate appropriate to the level of services performed. However, compliance with CLIA requirements is not assessed by surveyors conducting RHC surveys. Surveyors should, however, ask to see the RHC's CLIA certificate.

RHCs may also provide additional laboratory services, either on-site or through an off-site arrangement, but if it does so, these optional services must also comply with the CLIA requirements. For example, an RHC may have an arrangement with some other provider of clinical laboratory services. However, such arrangements are not permitted to substitute for the requirement to actually provide the 6 basic laboratory services within the RHC, by RHC staff.

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FED - J0136 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(c)(3)

Regulation Definition

491.9(c) Direct services

(3) Emergency. 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

Interpretive Guideline

491.9(c)(3)

The RHC ensures staff is available to appropriately handle medical emergencies at all times the clinic operates. The clinic maintains the types and quantity of drugs and biologicals typically used by first responders in accordance with accepted standards of practice. The RHC's patient care policies are expected to address which drugs and biologicals it maintains for emergencies and in what quantities. The regulation lists examples of such drugs and biologicals, and the RHC must maintain a supply of drugs and biologicals adequate to handle the volume and type of emergencies it typically encounters, in each of the following categories:

- Analgesics;
- Local Anesthetics;
- Antibiotics;
- Anticonvulsants; and
- Antidotes, emetics, serums & toxoids.

It is appropriate for a RHC to store a small volume of a particular drug/biological, if it generally handles only a small volume/type of a specific emergency. For example, if a RHC is located and region of the country that generally does not encounter snake bites and the RHC itself has not encountered such an emergency, it would be acceptable if the clinic maintain a smaller volume of an antidote.

FED - J0140 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Standard

CFR 491.9(d)

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Regulation Definition	Interpretive Guideline
491.9(d) Services provided through agreements or arrangements. (1) 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: (i) Inpatient hospital care; (ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and (iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center. (2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.	491.9(d) The clinic has referral agreements with at least one Medicare/Medicaid-participating: o Hospital or CAH, for inpatient acute care; o Physician; o Diagnostic testing facility (which could be a hospital or CAH or a freestanding diagnostic testing facility) for ambulatory diagnostic tests not furnished in the RHC; and o Clinical laboratory, for laboratory services not furnished in the RHC. The referral arrangements do not have to be in writing, but if they are not there must be evidence that RHC patients referred for additional services are being accepted and treated by the provider/supplier they are referred to.

FED - J0150 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

Type Condition

CFR 491.10

Regulation Definition	Interpretive Guideline
491.10 Patient health records	Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

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FED - J0151 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

Type Standard

CFR 491.10(a)(1)-(2)

Regulation Definition

491.10(a) Records system.

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

(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

Interpretive Guideline

491.10(a)(1)-(2)

The RHC must maintain a complete, comprehensive and accurate clinical record (also referred to as a medical record) for each RHC patient. The RHC must use the information contained in each clinical record in order to ensure the delivery of appropriate care to each RHC patient.

The RHC must have a designated member of its professional staff (which may be an administrative professional rather than a clinical professional) who is responsible for the RHC's clinical record system. That individual is responsible for developing and implementing, with approval of the RHC's professional staff and leadership, written clinical record policies and procedures.

A RHC that has an electronic health record (EHR) system may be part of a larger EHR system or may participate in a systematic exchange of patient health care information to promote good patient care. In either insistence, only the appropriate RHC staff may have access to the medical records of RHC patients. The RHC's written clinical records policies and procedures reflect that it is part of a larger system or exchange, when applicable. Further, even when the RHC participates in a larger EHR system, the clinical records for all RHC visits must still meet the requirements of the RHC Patient Health Records Condition and must be readily retrievable and distinguishable from other information in the shared EHR system.

The RHC must also comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules at 45 CFR Parts 160 and 164 when sharing clinical record information that is Protected Health Information. However, CMS does not interpret or assess compliance with HIPAA requirements, and thus surveyors also are not authorized to assess HIPAA compliance. If surveyors suspect a serious breach of HIPAA, they should refer their concerns to the regional U.S. Department of Health & Human Services Office of Civil Rights.

Complete and accurate

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All clinical records entries must be legible, i.e., able to be read clearly and unambiguously. Any entries or information contained in the clinical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

The clinical record must also be complete, i.e., it must contain for each patient at least the information required at § 491.10(a)(3). Implicit in the requirement for the record to be complete is an expectation that all entries of required information are made into the clinical record promptly, so that it is available to subsequent caregivers. The clinical record must be complete.

The RHC must ensure that all clinical records are accurately written. All clinical records must contain the correct information for the correct patient. The identity of the patient must be clear through use of identifiers such as name, date of birth, etc. The RHC may have a system in place that assigns a unique patient identifier to each patient, such as a medical record number or financial identification number. If the RHC has such a system in place, its clinical records policies and procedures must address the manner in which the unique identifiers are generated and assigned to each individual patient. The RHC must also take steps to ensure the accurate identity of the patients if using unique identifiers.

Entries in the clinical record may be made only by individuals authorized by the RHC in accordance with its written policies and procedures to do so, and must be dated, timed, and authenticated by the individual making the entry. When authenticating the entry, the author indicates by his/her signature/authentication that the entry is accurate. Entries made on behalf of a practitioner by authorized individuals must also be promptly dated, timed, and authenticated by the practitioner. A clinic policy stating that a practitioner must disapprove an entry within a specific time period or the entry is by "default" authenticated is not acceptable; the practitioner must affirmatively authenticate each entry.

The RHC must have in place a method to identify the author of each entry and to ensure that entries are not made by any individual using another individual's identity. For example, if the RHC uses an EHR system that requires individuals to use passwords or card keys to access the system, individuals may not share their passwords or card keys with other individuals. Likewise, if the RHC uses a paper clinical record system and authorizes the use of rubber stamps for signatures, the individual whose signature the stamp represents must not allow any other individual to use it.

Readily accessible

The clinical record must be readily accessible to RHC staff. The RHC must have a clinical record system that allows

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clinical staff timely access when needed to all open records, i.e., records of all RHC patients who, per clinical record policy, are considered to still be active RHC patients. The clinical records policies and procedures must also address how long closed clinical records will be readily accessible to staff (This is distinguishable from the 6 year retention of closed records requirement at §491.10(c)).

The RHC's clinical record system must be systematically organized to facilitate completion, storage, and retrieval of records in a manner that supports timely provision of evaluation or treatment services to RHC patients.

FED - J0152 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

Type Standard

CFR 491.10(a)(3)(i)-(iv)

Regulation Definition

491.10(a) Records system.

(3) For each patient receiving health care services, the clinic . . .. 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;

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

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

Interpretive Guideline

Interpretative Guidelines 491.10(a)(3)(i) - (iv)

The clinical record for each RHC patient must contain at least the following information:

Identification and Social Data

The clinical record must contain information that allows the identity of the patient to be clear through the use of patient identifiers such as name, date of birth, etc.

"Social data" may include the patient's address, work information, insurance information, names of family members, designated representative (if any), etc.

Informed Consent

The RHC must have written patient care policies that address the circumstances when the patient's informed consent to diagnosis or treatment is required, and under what emergency circumstances the informed consent requirement may be waived.

The clinical record must include a record of the patient's (or that of the patient's representative, determined in accordance with State law) informed consent in all cases where the RHC's policies require informed consent. If there

is applicable Federal or State law requiring informed consent, the RHC must comply with those requirements, but compliance is not assessed as part of the survey of the RHC's compliance with the CfCs.

The clinical record must provide evidence the informed consent was properly executed. A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the RHC's informed consent policies, all clinical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with RHC's policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

o Name of the specific procedure(s), or other type of diagnosis or treatment for which consent is being given;

o Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;

o Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's representative (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity). RHCs are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.

o Signature of the patient or the patient's representative; and

o Date and time the informed consent is signed by the patient or the patient's legal representative. If the RHC uses an EHR system, signature may be electronic. However, there must be documentation of how the patient's or representative's e electronic signature is verified within the EHR system and may not be altered. Likewise, there must be documentation that makes clear what the patient or representative consented to and how alteration is prevented.

o If there is applicable State law governing the content of the informed consent form, then the RHC's form must comply with those requirements.

Pertinent Medical History

The purpose of a medical history is to determine whether there is anything in the patient's overall condition that would

affect the patient's diagnosis or planned course of treatment, such as a prior occurrence of similar symptoms, a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce adverse health risks to the patient.

Only qualified personnel as determined by RHC policy may enter the medical history into the clinical record, but in all cases, the medical history must be reviewed and authenticated promptly by a practitioner. The RHC must have written policies and procedures specifying when a new or updated medical history is required.

Assessment of the Health Status and Health Care Needs of the Patient

The clinical record must include assessment by a practitioner of the current health status and health care needs of the patient at the time of each RHC visit.

Brief Summary of the Episode, Disposition, and Instructions to the Patient

There must be a brief summary of the reason for the RHC visit and the patient's disposition, including any follow-up instructions provided to the patient. Only qualified personnel as determined by RHC policy may enter the summary into the clinical record, but in all cases the summary must be authenticated promptly by a RHC practitioner.

Reports of Physical Examinations

Physical examinations performed on the patient are typically conducted at the time the pertinent medical history is being collected, but may also be conducted at other times. The physical examination must be completed by a practitioner and documented and authenticated in the clinical record by a practitioner in accordance with State law and RHC policy.

Diagnostic and Laboratory Test Results

All results of diagnostic and laboratory tests that are performed by the RHC directly or under arrangement must be included in the patient's clinical record. Any interpretations of tests by a practitioner must be authenticated by the practitioner.

Consultative Findings

All findings of a practitioner who provides consultation at the request of a RHC practitioner on a RHC patient, and

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who reports those findings to the RHC practitioner, must be included in the patient's clinical record.

Other Required Content

The clinical record must also contain:

o Practitioner's orders, dated, timed, and signed, for all tests, medications, treatments, and any other matters requiring an order from a practitioner;

o Nursing notes, properly authenticated, for all patients reflecting all nursing care provided;

o Documentation of all treatments furnished (including any complications that occurred) by the practitioner furnishing the c care;

o Documentation of all medications administered (including adverse drug reactions) by the person administering the medication;

o Documentation of the patient's response to all treatments furnished; and

o Evidence of other pertinent information required to monitor the patient's progress, such as vital signs.

FED - J0153 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

Type Standard

CFR 491.10(b)

Regulation Definition

491.10(b) Protection of record information.

(1) The clinic . . . maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and

Interpretive Guideline

491.10(b)

The RHC must have sufficient safeguards to ensure that access to all information regarding patients is limited to authorized individuals only. Whether in paper or electronic format, clinical records must be protected from loss or unintended destruction, and must be protected from access by unauthorized individuals or unauthorized used by authorized individuals. However, the nature of the safeguards the RHC uses will vary depending on the medium in which records are created and stored. For example, closed paper records might be locked in a secure area that is

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removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

protected from environmental hazards, such as fire, floods, humidity, etc., while open paper records might be kept in an area where access is limited to authorized personnel. On the other hand, safeguards for EHR systems might be focused on back-up electrical power, arrangements for backing up information at a remote server, and limiting access through use of passwords, card readers, etc.

The RHC's clinical record policies and procedures must address who may use clinical records, how they may use them, who may "remove" clinical records (i.e., physically removing paper records or films, or deleting records from an EHR system), and under which conditions information in a clinical record may be released, and to whom.

Prior to releasing information from their clinical record, the RHC must obtain the written consent of the patient who is the subject of the record (or his/her representative), unless the release is required by law. Note that uses and disclosures of protected health information (PHI) which are, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR parts 160 and 164, Subparts A and E), made without the patient's prior authorization are considered to also be permissible under the RHC CfCs and do not require the written authorization specified in § 491.10(b)(3). Note that CMS and State surveyors conducting surveys on behalf of CMS are not authorized to assess compliance with the HIPAA Privacy Rule, which is interpreted and enforced by the U.S .Department of Health and Human Services Office of Civil Rights (OCR). If surveyors and their managers have concerns about disclosures that the RHC makes without the written consent of the patient (or the patient's representative), they should refer such concerns to the Regional OCR office.

FED - J0154 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

Type Standard

CFR 491.10(c)

Regulation Definition

491.10(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.

Interpretive Guideline

491.10(c)

Clinical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The RHC must be able to promptly retrieve the complete medical record of every individual evaluated or treated at the RHC 6 years after the latest entry made into the patient's record. Therefore, clinical records must be maintained within the RHC.

Although RHCs are expected to comply with other Federal or State law requirements calling for longer retention

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periods, compliance with these other requirements is not assessed as part of the Federal RHC survey.

FED - J0160 - PROGRAM EVALUATION

Title PROGRAM EVALUATION

Type Condition

CFR 491.11

Regulation Definition	Interpretive Guideline
§491.11 Program evaluation.	§ 491.11 Program Evaluation Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance.

FED - J0161 - PROGRAM EVALUATION

Title PROGRAM EVALUATION

Type Standard

CFR 491.11(a)-(c)

Regulation Definition	Interpretive Guideline
§ 491.11 Program evaluation. (a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program. (b) The evaluation includes review of: (1) The utilization of clinic or center services, including at least the number of patients served and the volume of services; (2) A representative sample of both active and closed clinical records; and	Interpretative Guidelines §491.11(a)-(c) The clinic's program evaluation must be reviewed at least biennially. This evaluation may be done by RHC staff or through arrangement with other appropriate professionals. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so. The evaluation must include, at a minimum, the number of patients served and the volume of services provided. The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population. It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted. The evaluation does not have to be done all at once or by the same individuals. However, if the evaluation is not performed all at once, no more than one year may elapse between evaluating the same components. A RHC that has been certified for less than one year

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(3) The clinic's or center's health care policies.

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

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

may not have done a program evaluation. However, the RHC must have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered within the evaluation.

The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC's current patients or 50 records, whichever is less. The purpose of the review is to determine whether utilization of the RHC's services was appropriate, i.e., whether practitioners adhere to accepted standards of practice and adhere to the RHC's guidelines for medical management when diagnosing or treating patients. The review also must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies. The evaluation of practitioners must be conducted by an MD or DO; if there is only one MD or DO practicing in the RHC, it is expected that the RHC will arrange for an outside MD/DO to review the selected sample of records of RHC patients cared for by the RHC's MD/DO. The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.

The evaluation findings must be documented in a summary report, and must include recommendations, if any, for corrective actions to address problems identified in the evaluation. If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.

FED - J0162 - PROGRAM EVALUATION

Title PROGRAM EVALUATION

Type Standard

CFR 491.11(d)

Regulation Definition

491.11(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

Interpretive Guideline

Interpretative Guidelines § 491.11(d)

The RHC's leadership must consider the evaluation findings and recommendations for change, if any. It must take corrective actions as necessary, such as changes in policies or, with respect to clinical personnel, provision of additional training, changes in level of supervision, or even limiting or terminating clinical privileges. The RHC must document where and when the evaluation findings and recommendations were considered, and by whom they were considered. It must also document what corrective actions, if any, were taken and by whom they were recommended. If the RHC leadership does not take corrective actions recommended as part of the evaluation, or if it takes corrective actions different from those recommended, it must document the rationale for its decision.

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FED - J9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition	Interpretive Guideline