Aspen Federal Regulation Set: J 07.02 RURAL HEALTH CLINIC

FED - J0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

CFR

Type Memo Tag

Regulation Definition

Interpretive Guideline

FED - J0003 - COMPLIANCE WITH FED,STATE,& LOCAL LAWS

Title COMPLIANCE WITH FED,STATE,& LOCAL LAWS

CFR 491.4

Type Condition

Regulation Definition

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

Interpretive Guideline

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

State Laws and Regulations.--All States have practice acts that govern the activities of health professionals. While there is considerable variation in the States' practice acts concerning physician assistants, nurse practitioners and certified nurse-midwives, there is a broad mandate in the medical practice acts of all States giving physicians authority to diagnose and treat medical conditions. The extent to which the physician may delegate these responsibilities and to whom, and under what conditions, varies in the States. Some States have updated their practice acts since the advent of the physician assistant, nurse practitioner and certified nurse-midwife health care professionals. In some instances, these updated practice acts have included definitions and specific references to permitted/prohibited activities; supervision/guidance required by a physician, and location/situations in which nurse practitioners, certified nurse-midwives and physician assistants may function. In some States where nurse practice acts have not been significantly updated, some functions of the nurse practitioner are viewed as an extension of the traditional nursing role as being covered by the existing nurse practice act.

Rural health clinics can be certified only if the State permits--that is, does not explicitly prohibit--the delivery of primary health care by a nurse practitioner, certified nurse-midwife or a physician assistant. The surveyor will encounter wide variations in the wording, interpretation, and application of States' practice acts as they affect the

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physician assistant, nurse practitioner and certified nurse-midwife in the RHC setting.

In situations where the State law is silent, or where the State law does not specifically prohibit the functioning of a physician assistant, nurse practitioner or certified nurse-midwife with medical direction by a physician and with the degree of supervision, guidance, and consultation required by the RHC regulations, the surveyor may consider this condition as being met. Interpretations needed on specific aspects of the State's practice act should be sought through the State regulatory agency or board(s) dealing with the practice and profession.

FED - J0004 - LICENSURE OF CLINIC

Title LICENSURE OF CLINIC

CFR 491.4(a)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... is licensed pursuant to applicable State and local law	

FED - J0005 - LICENSURE/CERT/REGISTRATION OF PERSONNEL

Title LICENSURE/CERT/REGISTRATION OF PERSONNEL

CFR 491.4(b)

Type Standard

Regulation Definition	Interpretive Guideline
Staff of the clinic ... are licensed, certified or registered in accordance with applicable State and local laws.	

FED - J0006 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

CFR 491.5

Type Condition

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Regulation Definition	Interpretive Guideline
Location of Clinic	

FED - J0007 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.5(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
An RHC is located in a rural area that is designated as a shortage area	Consult with the RO to preliminarily ascertain that a clinic meets the basic requirement of location prior to scheduling a survey. The clinic must be located in a rural area that is designated as a shortage area. Applicants determined not qualified under this requirement should be sent a letter (see Exhibit 27) with the appropriate notation.

FED - J0008 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

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

Type Standard

Regulation Definition	Interpretive Guideline
(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 a permanent structure. (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	

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FED - J0009 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.5(a)(3)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[(3) ...the RHC ... may be permanent or mobile units.] (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).	C - Mobile Units A mobile unit must meet the Conditions for Certification for it to qualify as a RHC. In addition, it should be ascertained that the mobile unit has fixed scheduled locations, each of which meet the rural and shortage area requirements. Since the mobile unit is a clinic, it is expected that the RHC services are provided in the unit and not in a permanent structure, with the unit serving only as a mobile repository for the equipment, supplies, and records. The only exception would be if the RHC services were furnished off the clinic ' s premises (away from the unit) to homebound patients. Where a facility offers RHC services at a permanent structure as well as in a mobile unit, each facility must be certified separately as a RHC. This is differentiated from the situation where a permanent structure provides RHC services off the premises, e.g., to homebound patients, with the use of a vehicle to transport supplies, equipment, records, and staff.

FED - J0010 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

CFR 491.5(b)

Type Standard

Regulation Definition	Interpretive Guideline
Exceptions: [to location requirements]	

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FED - J0011 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

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

Type Standard

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

FED - J0012 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

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

Type Standard

Regulation Definition	Interpretive Guideline
(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.	

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FED - J0013 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)

Type Standard

Regulation Definition

Criteria for designation of rural areas

Interpretive Guideline

FED - J0014 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)(1) - (2)

Type Standard

Regulation Definition

(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 designed by the Census Bureau as urban.
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Interpretive Guideline

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FED - J0015 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)(3)

Type Standard

Regulation Definition	Interpretive Guideline
Included in the classification of rural areas are those portions of extended cities that the Census Bureau has determined to be rural.	

FED - J0016 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)

Type Standard

Regulation Definition	Interpretive Guideline
Criteria for designation of shortage areas.	

FED - J0017 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:	

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(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.

FED - J0018 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)(2) and (e)

Type Standard

Regulation Definition

(d)(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Service 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.

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

Interpretive Guideline

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

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

FED - J0019 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

CFR 491.6

Type Condition

Regulation Definition	Interpretive Guideline
Physical plant and environment.	

FED - J0020 - CONSTRUCTION

Title CONSTRUCTION

CFR 491.6(a)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ...is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.	A - Physical Plant Safety To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review. Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.

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FED - J0021 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... has a preventive maintenance program to ensure that:	B - Preventive Maintenance A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)) and inspection of the facility to assure that services are rendered in a clean and orderly environment. Inspection schedules and reports should be available for review by the surveyor.

FED - J0022 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;	

FED - J0023 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Drugs and biologicals are appropriately stored; and	

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FED - J0024 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The premises are clean and orderly.	

FED - J0025 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)

Type Standard

Regulation Definition	Interpretive Guideline
Emergency procedures. The clinic ... assures the safety of patients in case of non-medical emergencies by:	C - Non-Medical Emergencies Review written documentation and interview clinic personnel to determine what instructions for non-medical emergency procedures have been provided and whether clinic personnel are familiar with appropriate procedures. Non-medical emergency procedures may not necessarily be the same for each clinic.

FED - J0026 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Training staff in handling emergencies.	

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FED - J0027 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Placing exit signs in appropriate locations; and	

FED - J0028 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(3)

Type Standard

Regulation Definition	Interpretive Guideline
Taking other appropriate measures that are consistent with the particular conditions with the area in which the clinic ... is located.	

FED - J0029 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

CFR 491.7

Type Condition

Regulation Definition	Interpretive Guideline
Organizational structure.	

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FED - J0030 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)

Type Standard

Regulation Definition	Interpretive Guideline
Basic requirements	

FED - J0031 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... is under the medical direction of a physician and has a health care staff that meets the requirements of §491.8.	Basic Requirements Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of §491.8, and has adequate written material covering organization policies, including lines of authority and responsibilities.

FED - J0032 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.	Written Policies Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may

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cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic ' s operation.

FED - J0033 - DISCLOSURE

Title DISCLOSURE

CFR 491.7(b)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... discloses the names and addresses of:	Disclosure of Names and Addresses The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction. Any entity may organize itself as an owner of a RHC. The types of organizations being referred to are described in answers to question IV on the Request to Establish Eligibility. These range from: o A physician in a private general practice located in a shortage area who employs either a nurse practitioner, certified nurse-midwife or a physician assistant; o A nurse practitioner, certified nurse-midwife or a physician assistant in solo practice in a shortage area who develops the required relationship with a physician for medical direction; to o Organizations either for profit or not for profit who own primary care clinics located in shortage areas. Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the State.

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FED - J0034 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);	

FED - J0035 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The person principally responsible for directing the operation of the clinic ...; and	

FED - J0036 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The person responsible for medical direction.	

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FED - J0037 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

CFR 491.8

Type Condition

Regulation Definition	Interpretive Guideline
Staffing and staff responsibilities	

FED - J0038 - STAFFING

Title STAFFING

CFR 491.8(a)

Type Standard

Regulation Definition	Interpretive Guideline
Staffing	A - Sufficient Staffing The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When staffing meets the minimum requirement but appears insufficient for the services the RHC provides, explain, with reasonable detail, the circumstances (and RHC's efforts to overcome them) that make employment of additional needed staff not possible. Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain the services of a physician on a permanent basis, as well as arrangements it has made for immediate temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification. The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic.

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However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services on the clinic's premises (including a mobile unit) at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant 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 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 other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic offers RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services during all 28 hours . Of these

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28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 14 hours (50 percent of 28 hours) to furnish patient care services.

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 the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when its schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 9 hours to furnish patient care services. This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant 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.

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

FED - J0039 - STAFFING

Title STAFFING

CFR 491.8(a)(1)

Type Standard

Regulation Definition

The clinic ... has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

Interpretive Guideline

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently

are not able to employ what would be considered sufficient health care staffs. When staffing meets the minimum requirement but appears insufficient for the services the RHC provides, explain, with reasonable detail, the circumstances (and RHC's efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain the services of a physician on a permanent basis, as well as arrangements it has made for immediate temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services on the clinic's premises (including a mobile unit) at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant 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 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 other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic offers RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services during all 28 hours . Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 14 hours (50 percent of 28 hours) to furnish patient care services.

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 the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when its schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 9 hours to furnish patient care services. This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant 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.

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

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FED - J0040 - STAFFING

Title STAFFING

CFR 491.8(a)(2) - (4)

Type Standard

Regulation Definition

(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.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic ..., or 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.

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

Interpretive Guideline

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When staffing meets the minimum requirement but appears insufficient for the services the RHC provides, explain, with reasonable detail, the circumstances (and RHC's efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain the services of a physician on a permanent basis, as well as arrangements it has made for immediate temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which

would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services on the clinic's premises (including a mobile unit) at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant 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 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 other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic offers RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services during all 28 hours . Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 14 hours (50 percent of 28 hours) to furnish patient care services.

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 the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when its schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 9 hours to furnish patient care services. This requirement would be met if a nurse practitioner, certified nurse-midwife or physician

assistant 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.

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

FED - J0041 - STAFFING

Title STAFFING

CFR 491.8(a)(6)

Type Standard

Regulation Definition

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic... operates. In addition, 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

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When staffing meets the minimum requirement but appears insufficient for the services the RHC provides, explain, with reasonable detail, the circumstances (and RHC's efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain the services of a physician on a permanent basis, as well as arrangements it has made for immediate temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

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The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services on the clinic's premises (including a mobile unit) at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant 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 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 other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic offers RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified

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nurse-midwife, or a physician assistant must be available to furnish patient care services during all 28 hours . Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 14 hours (50 percent of 28 hours) to furnish patient care services.

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 the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when its schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 9 hours to furnish patient care services. This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant 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.

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

FED - J0042 - STAFFING

Title STAFFING

CFR 491.8(a)(5)

Type Standard

Regulation Definition

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

Interpretive Guideline

A - Sufficient Staffing

The staffing described in 42 CFR 491.8(a) is the minimum-staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in

areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When staffing meets the minimum requirement but appears insufficient for the services the RHC provides, explain, with reasonable detail, the circumstances (and RHC's efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide documentation showing its good faith effort to obtain the services of a physician on a permanent basis, as well as arrangements it has made for immediate temporary physician services to perform the required physician responsibilities. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification.

The regulation requires that at least one physician assistant, or nurse practitioner is an employee of the clinic. However, if the clinic has more than one non-physician practitioner on staff, the other practitioners may furnish services under contract to the clinic instead of being employees.

If a currently certified RHC loses its non-physician practitioner(s) and is unable to meet the requirement for a minimum 50 percent availability of such practitioners during the RHC's operating hours, it may request a temporary staffing waiver. The RHC must demonstrate its inability to recruit a replacement within the 90-day period prior to its application for a waiver. Only currently certified RHCs may request a waiver. CMS may not approve any waiver request submitted less than six months after the expiration of a previous waiver. Eligible waiver requests are deemed granted unless denied by the CMS regional office within 60 days of receipt.

It is the responsibility of the clinic to promptly advise the State Survey Agency of any changes in staffing which would affect its certification status.

B - Staffing Availability

A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)) or physician assistant must be available to furnish patient care services on the clinic's premises (including a mobile unit) at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant 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 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 other residential facility.), the time spent providing RHC services outside the clinic may be counted towards the 50 percent requirement.

For any portion of the RHC's schedule when neither a physician assistant, nor a certified nurse-midwife, nor a nurse practitioner is available, a physician must be available on-site to provide needed services in order for the RHC to be open and operating.

The following are examples of how determinations regarding these requirements may be made. A clinic offers RHC services from 10 to 5 Tuesday through Friday, 28 hours a week. A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services during all 28 hours . Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 14 hours (50 percent of 28 hours) to furnish patient care services.

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 the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when its schedule offering RHC services is very limited. An example would be a clinic where RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available on-site at the clinic (including in a mobile unit) or providing RHC services in the patient's residence at least 9 hours to furnish patient care services. This requirement would be met if a nurse practitioner, certified nurse-midwife or physician assistant 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.

C - Staff Responsibilities

The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

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FED - J0045 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)

Type Standard

Regulation Definition

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

Interpretive Guideline

Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

o Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.

o Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.

o Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

A physician member must perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at 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, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

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FED - J0046 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(1)

Type Standard

Regulation Definition

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

Interpretive Guideline

Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

o Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.

o Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.

o Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

A physician member must perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at 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, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

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FED - J0047 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(2)

Type Standard

Regulation Definition

(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.

Interpretive Guideline

Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

o Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.

o Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.

o Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

A physician member must perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at 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, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

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FED - J0048 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(3)

Type Standard

Regulation Definition

(3) Periodically reviews the clinic's ... patient records, provides medical orders, and provides medical care services to the patients of the clinic ... .

Interpretive Guideline

Physician Responsibilities

In accordance with §491.8(b), the physician performs the following:

o Provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, except for services furnished by a clinical psychologist in an FQHC, if State law permits them to be provided without physician supervision.

o Together with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and procedures governing the clinic's patient care services.

o Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

A physician member must perform the duties and responsibilities described in 42 CFR 491.8(b)(1), (2), and (3), but does not need to be on-site in order to perform all of these duties, unless there are times during the RHC's operating hours when no nurse practitioner, certified nurse-midwife or physician assistant is present at 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, and medical care services, including being on-site at the facility. The regulation allows for use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. A State or the RHC itself is not precluded from establishing requirements for physician supervision of non-physician practitioners that are more stringent, but these requirements are not enforced through the Federal Medicare certification process.

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FED - J0050 - PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

Title PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

CFR 491.8(c)

Type Standard

Regulation Definition	Interpretive Guideline
Physician assistant and nurse practitioner responsibilities	Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is performing the necessary responsibilities at 42 CFR 491.8(c)(1) and (2).

FED - J0051 - PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

Title PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

CFR 491.8(c)(1) - (2)

Type Standard

Regulation Definition	Interpretive Guideline
(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; (ii) Participate with a physician in a periodic review of the patients heath records. (2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed	Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is performing the necessary responsibilities at 42 CFR 491.8(c)(1) and (2).

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by a physician:

(i) Provide 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.

FED - J0052 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

CFR 491.9

Type Condition

Regulation Definition

Provision of services

Interpretive Guideline

A. Basic Requirements

l. State and Local Laws.--Know the State's position, generally, with respect to implementing the Federal RHC requirements vis-a-vis the State's Medical Practice Act, Nurse Practice Act, the Pharmacy Act, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91- 513) and the general scope of practice permitted for nurse practitioners, certified nurse-midwives and physician assistants.

Some States may have legal impediments because applicable practice acts prohibit nurse practitioners, certified nurse-midwives and/or physician assistants from independent acts of medical diagnosis and treatment precluding the fullest implementation of the Federal RHC requirements.

This does not necessarily preclude participation by a RHC that provides RHC services (physician-type services) furnished by nurse practitioners, certified nurse-midwives and/or physician assistants under the direct supervision (as distinguished from indirect supervision) of a physician. Therefore, inquiries to State authorities about compliance with the Federal RHC requirements, as well as decisions concerning applicant RHCs, must be weighed against several determinations, including:

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o The medical direction and supervision described in the regulations is the minimum requirement; many participating RHCs operate with greater medical direction and supervision than these minimums.
o The word "supervision" does not automatically equate with direct, over the shoulder supervision. Many States requiring physician supervision of medical acts performed by a nurse practitioner or a physician assistant have held that performances of such medical acts under written patient care guidelines developed and/or approved by a licensed physician satisfy the requirement of supervision.

FED - J0053 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.9(a)(1) - (3)

Type Standard

Regulation Definition

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

(2) The clinic ... is primarily engaged in providing outpatient health services and meets all other conditions of this subpart

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

Interpretive Guideline

2. Providing Rural Health Clinic Services.--The law describes a RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services; usually, related health care services such as the "other ambulatory services" covered by Medicaid State plans. Certification as a RHC applies to the facility as a whole and the total operating schedule of the facility (the hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services. If onsite observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician's office), then the clinic may satisfy the "primarily engaged" requirement providing that RHC services are offered at least 51 percent of the total operating schedule. The time RHC services are offered may differ from the total operating schedule of the facility, but may not be less than 51 percent of this total operating schedule.

If there is a question about this condition, review a sample of patient health records covering a reasonable period of time to determine the majority of specific services actually furnished.

An example of a clinic schedule that combines RHC services and "other ambulatory services" would be a clinic in which primary medical care is offered from 9 to 4 Monday through Thursday, and dental services are offered from 9 to 4 on Friday.

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FED - J0054 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)

Type Standard

Regulation Definition	Interpretive Guideline
Patient care policies	B. Patient Care Polices Requirements.--Review the clinic's policies and ascertain who developed them. Where changes in clinic personnel and/or clinic administration make it impossible or not relevant to ascertain who developed the policies, it is necessary to ascertain that the current physician member(s) and the nurse practitioner, certified nurse-midwife, and/or physician assistant member(s) of the staff have an in-depth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed- to written changes in them. If a clinic's organizational structure includes a governing body, ascertain whether the governing body has ultimate authority in approving the patient care policies and, if so, when such approval was last given. While clinics frequently seek the participation of other health care professionals in developing patient care policies (particularly the written guidelines for the medical management of health problems) the term "a group of professional personnel" is not restricted to health care professionals. In some cases, the clinic will have involved health care professionals representatives to a hospital with which the clinic has an agreement for patient referral. In any event, one member of the group of three or more may not be a member of the clinic's staff, and professions which are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.

FED - J0055 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic's ... health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.	

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FED - J0056 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician's assistants or nurse practitioners. At least one member of the group is not a member of the clinic ...staff.	

FED - J0057 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
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 ...; and (iii) Rules for the storage, handling, and administration of drugs and biologicals.	The requirements concerning written policies address four areas: 1. Description of Services.--A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. The services furnished by the clinic should be described in a manner than informs potential patients of the types of health care available at the clinic, as well as setting the parameters of the scope of what services are furnished through referral. Such statements as the following 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, complete dental care, emergency medical care. Statements such as "complete management of common acute and chronic health problems" standing alone, do not sufficiently describe services. Additional services, furnished through referral, are sufficiently described in such statements as: Arrangements have been made with X hospital for clinic patients to receive the following services if required: specialized diagnostic and

laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.

2. Guidelines for Medical Management.--The clinic's written guidelines for the medical management of health problems include a description of the scope of medical acts which may be undertaken by the physician assistant, certified nurse-midwife, and/or nurse practitioner. They represent an agreement between the physician providing the clinic's medical direction and the clinic's physician assistant, certified nurse-midwife, and/or nurse practitioner on the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken without direct, over the shoulder physician supervision. They describe the regimens to be followed and stipulate the conditions in the illness or health care management at which consultation or referral is required.

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.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements. They:

o Are comprehensive enough to cover most health problems that patients usually see a physician about;
o Describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant;
o Describe the medical conditions, signs, or developments that require consultation or referral; and
o Are compatible with applicable State laws.

A number of patient care guidelines have been published by members of the medical profession. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the essential elements described above.

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3. Drugs and Biologicals.--Written policies cover at least the following elements:

o Requirements dealing with the storage of drugs and biologicals in original manufacturer's containers to assure that they maintain their proper labeling and packaging;
o Requirements dealing with outdated, deteriorated, or adulterated drugs and biologicals being stored separately so that they are not mistakenly used in patient care prior to their disposal in compliance with applicable laws;
o Requirements dealing with storage in a space that provides proper humidity, temperature, and light to maintain the quality of drugs and biologicals;
o Requirements for a securely constructed locked compartment for storing drugs classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970;
o Requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV, and V; with Schedule II drugs being accounted for separately;
o Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;
o Requirements dealing with the complete and legible labeling of containers used to dispense drugs and biologicals to patients;
o Requirements concerning the availability of current drug references and antidote information; and
o Requirements dealing with prescribing and dispensing drugs in compliance with applicable State laws.

FED - J0058 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(4)

Type Standard

Regulation Definition

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

Interpretive Guideline

4. Review of Policies.--The group of professional personnel, which can be the governing body acting as the group, is responsible for an annual review of patient care policies.

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FED - J0059 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 491.9(c)

Type Standard

Regulation Definition	Interpretive Guideline
Direct services	C. Direct Services.--The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services which must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.

FED - J0060 - DIRECT SERVICES - GENERAL

Title DIRECT SERVICES - GENERAL

CFR 491.9(c)(1)

Type Standard

Regulation Definition	Interpretive Guideline
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. .	

FED - J0061 - DIRECT SERVICES - LABORATORIES

Title DIRECT SERVICES - LABORATORIES

CFR 491.9(c)(2)

Type Standard

Aspen Federal Regulation Set: J 07.02 RURAL HEALTH CLINIC

Regulation Definition

Laboratory. These requirements apply to RHCs but not ... 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 methods 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

The clinic's laboratory is to be treated as a physician's office for the purpose of licensure and meeting health and safety standards. The listed laboratory services are considered essential for the immediate diagnosis and treatment of the patient. To the extent they can be provided under State and local law, the nine services listed in J61, CMS-30, are considered the minimum the clinic should make available through use of its own resources.

If any of these laboratory services cannot be provided at the clinic under State or local law, that laboratory service is not required for certification. Some clinics are not able to furnish the nine services, even though they may be allowed to do so under State and local law, without involving an arrangement with a Medicare approved laboratory.

Those clinics unable to furnish all nine services directly when allowed to by State and local law should be given deficiencies. Such deficiencies should not be considered sufficiently significant to warrant termination if the clinic has an agreement or arrangement with an approved laboratory to furnish the basic laboratory service it does not furnish directly, especially if the clinic is making an effort to meet this requirement.

FED - J0062 - DIRECT SERVICES - EMERGENCY

Title DIRECT SERVICES - EMERGENCY

CFR 491.9(c)(3)

Type Standard

Regulation Definition

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

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FED - J0063 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)

Type Standard

Regulation Definition

Services provided through agreements or arrangements.

Interpretive Guideline

FED - J0064 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)(1)

Type Standard

Regulation Definition

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 ... .

Interpretive Guideline

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FED - J0065 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)(2)

Type Standard

Regulation Definition	Interpretive Guideline
If the agreements are not in writing, there is evidence that patients referred by the clinic ... are being accepted and treated.	

FED - J0066 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

CFR 491.10

Type Condition

Regulation Definition	Interpretive Guideline
Patient health records	

FED - J0067 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)

Type Standard

Regulation Definition	Interpretive Guideline
Records system	A. Records System.--The clinic is to maintain patient health records in accordance with its written policies and procedures. These records are the responsibility of a designated member of the clinic's professional staff and should be maintained for each person receiving health care services. All records should be kept at the clinic site so that they are available when patients may need unscheduled medical care.

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Examine a randomly selected sample of health records to determine if appropriate information, as related in J70 of the SRF and 42 CFR 491.10(a)(3), is included. This listing is the minimum requirement for record maintenance. If deficiencies are found while reviewing the records, review additional records to determine the prevalence of these deficiencies.

Record on the SRF the number of records reviewed and deficiencies found, if any, and as questions arise concerning the records, discuss them with the person responsible for record maintenance

FED - J0068 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... maintains a clinical record system in accordance with written policies and procedures.	

FED - J0069 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
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.	

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FED - J0070 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(3)

Type Standard

Regulation Definition	Interpretive Guideline
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.	

FED - J0071 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)

Type Standard

Regulation Definition	Interpretive Guideline
Protection of record information.	B. Protection of Record Information.--The clinic must ensure the confidentiality of the patient's health records and

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provide safeguards against loss, destruction, or unauthorized use of record information. Ascertain that information regarding the use and removal of records from the clinic and the conditions for release of record information is in the clinic's written policies and procedures. The patient's written consent is necessary before any information not authorized by law may be released.

FED - J0072 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.	

FED - J0073 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Written policies and procedures govern the use and removal of records from the clinic ... and the conditions for release of information.	

FED - J0074 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(3)

Type Standard

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Regulation Definition	Interpretive Guideline
The patient's written consent is required for release of information not authorized to be released without such consent.	

FED - J0075 - RETENTION OF RECORDS

Title RETENTION OF RECORDS

CFR 491.10(c)

Type Standard

Regulation Definition	Interpretive Guideline
The patient's records are retained for at least 6 years from the date of last entry, and longer if required by State statute.	C. Retention of Records.--Review the clinic policy pertaining to the retention of patient health records. This policy reflects the necessity of retaining records at least 6 years from the last entry date or longer if required by State statute.

FED - J0076 - PROGRAM EVALUATION

Title PROGRAM EVALUATION

CFR 491.11

Type Condition

Regulation Definition	Interpretive Guideline
Program Evaluation	An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other appropriate professionals. The surveyor clarifies for the clinic that the State survey does not constitute any part of this program evaluation. The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same personnel. However, if the evaluation is not done all at once, no more than a year should elapse between evaluating the same parts. For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of each fiscal year; and its utilization of clinic services, clinic records, and health care

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policies evaluated 6 months later by a group of health care professionals.

If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.

A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should 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 in the evaluation. What will be covered should be consistent with the requirements of 42 CFR 491.11. Record this information under the explanatory statements on the SRF.

Review dated reports of recent program evaluations to verify that such items are included in these evaluations. When corrective action has been recommended to the clinic, verify that such action has been taken or that there is sufficient evidence indicating the clinic has initiated corrective action.

FED - J0077 - ANNUAL TOTAL PROGRAM EVALUATION

Title ANNUAL TOTAL PROGRAM EVALUATION

CFR 491.11(a)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... carries out, or arranges for an annual evaluation of its total program.	

FED - J0078 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)

Type Standard

Regulation Definition	Interpretive Guideline
The evaluation includes a review of:	

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FED - J0079 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The utilization of clinic ... services, including at least the number of patients served and the volume of services;	

FED - J0080 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A representative sample of both active and closed clinical records; and	

FED - J0081 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic's ... health care policies.	

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FED - J0082 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)

Type Standard

Regulation Definition **Interpretive Guideline**

The purpose of the evaluation is to determine whether:

FED - J0083 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(1)

Type Standard

Regulation Definition **Interpretive Guideline**

The utilization of services was appropriate;

FED - J0084 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(2)

Type Standard

Regulation Definition **Interpretive Guideline**

The established policies were followed; and

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FED - J0085 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(3)

Type Standard

Regulation Definition	Interpretive Guideline
Any changes are needed.	

FED - J0086 - EVALUATION FINDINGS & ACTION TAKEN

Title EVALUATION FINDINGS & ACTION TAKEN

CFR 491.11(d)

Type Standard

Regulation Definition	Interpretive Guideline
The clinic ... staff considers the findings of the evaluation and takes corrective action if necessary.	

FED - J9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

CFR

Type Memo Tag

Regulation Definition	Interpretive Guideline