
CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare &
Medicaid Services (CMS)

Transmittal 223

Date: June 7, 2024

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix G - RHC

I. SUMMARY OF CHANGES: This transmittal includes revisions to the SOM Appendix G based on the recent federal regulation changes based on the CY 2024 Physician Fee Schedule final rule that was published on November 16, 2023, and titled *Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program*. The regulations in the final rule are effective as of January 1, 2024

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 7, 2024

IMPLEMENTATION DATE: June 7, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix G/J-0082/[§ 491.8(a) Staffing.]/§491.2 Definitions. As used in this subpart, unless the context indicates otherwise: Nurse practitioner means a person who meets the applicable State requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions: (1) Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master’s or doctoral degree in nursing practice; or...
R	Appendix G/J-0083/[§ 491.8(a) Staffing.]/(3) The . . . certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor 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 or center...

	<p>§491.2 Definitions. As used in this subpart, unless the context indicates otherwise:</p> <p><i>Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.</i></p> <p><i>Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.</i></p> <p><i>Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.</i></p> <p>Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at § 410.53 of this chapter.</p> <p><i>Mental health counselor means an individual who meets the applicable education, training, and other requirements at § 410.54 of this chapter.</i></p>
R	<p>Appendix G/J-0085/[§ 491.8(a) Staffing.]/(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor is available to furnish patient care services at all times the clinic or center operates. . . .</p>

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Or

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
**Appendix G - Guidance for Surveyors: Rural Health
Clinics (RHCs)**

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(Rev. 223; Issued: 06-07-24)

J-0082

(Rev. 223; Issued: 06-07-24; Effective: 06-07-24; Implementation: 06-07-24)

[§ 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.

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

Nurse practitioner means a *person* who meets the *applicable* State requirements governing the qualifications of nurse practitioners, and who meets *at least* one of the following conditions:

(1) Is certified as a nurse practitioner by *a recognized national certifying body that has established standards for nurse practitioners and possesses a master’s or doctoral degree in nursing practice*; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

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

Interpretative Guidelines § 491.8(a)(1) & (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.

- 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:

- The RHC submits the written request for a waiver to the appropriate SA;
- The RHC demonstrates that it has been unable, despite reasonable efforts, to hire a NP or PA in the previous 90-day period; and
- 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

Survey Procedures § 491.8(a)(1) & (3)

- Determine that the clinic has at the time of the survey at least one NP or PA who is an employee of the clinic, as evidenced by the clinic issuing a W-2.
- If the clinic already participates in Medicare as an RHC and does not employ a NP or PA, check whether there is a valid waiver in effect.

J-0083

(Rev. 223; Issued: 06-07-24; Effective: 06-07-24; Implementation: 06-07-24)

[§ 491.8(a) Staffing.]

(3) The . . . *certified* nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor 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

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

Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.

Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at § 410.53 of this chapter.

Mental health counselor means an individual who meets the applicable education, training, and other requirements at § 410.54 of this chapter.

Interpretative Guidelines § 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.

Survey Procedures § 491.8(a)(3)

- If the clinic has a nurse midwife, clinical social worker, or clinical psychologist on staff, verify that the individual has a current State license when one is required under State law.

J-0085

(Rev. 223; Issued: 06-07-24; Effective: 06-07-24; Implementation: 06-07-24)

[§ 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, clinical psychologist, *marriage and family therapist, or a mental health counselor* is available to furnish patient care services at all times the clinic . . . operates. . . .

Interpretative Guidelines § 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 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 telecommunications, 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.

Survey Procedures § 491.8(a)(5) & (6)

- Determine whether there is a physician or a non-physician practitioner on-site at all times the RHC is open. Review staff schedules and the clinic's hours of operation to confirm. Ask staff members if the RHC is ever open and providing services when no practitioner is present.
- Verify posted hours to confirm appropriate professional healthcare staffing within the RHC's hours of operation.