

Survey Procedures Within the State Operations Manual Appendix G - Guidance for Surveyors: Rural Health Clinics (RHCs) (Rev. 200, 02-21-20)

<https://www.cms.gov/files/document/appendix-g-state-operations-manual>

Survey Procedures § 491.3 & § 405.2412

~ Ask the leadership of the RHC, and physician(s) at the RHC when applicable, whether or not physician services are ever provided outside the RHC facility. If yes, ask the RHC to see the written agreement(s) and determine whether it contains the required provisions governing payment, certification and Medicare cost reporting.

Survey Procedures § 491.3 & § 405.2416 - §2417

Review personnel files of staff making VNS visits, to ensure that they are currently licensed as either an RN or an LPN.

Review a sample of records of patients receiving VNS to determine:

- ~ Whether there is a written treatment plan for each patient, established and signed by an RHC physician or non-physician practitioner;
- ~ Whether there is evidence that the plan was reviewed by an RHC physician at least every 60 days;
- ~ Whether the clinical record documents the provision of VNS to the patient in accordance with the written plan for that patient.
- ~ Observe at least one VNS visit, if any have been scheduled during the survey period, to determine whether care is being provided in accordance with the written treatment plan for that patient.

Survey Procedures § 491.4(a)

- ~ Prior to the survey, determine whether the RHC is subject to State or local licensure requirements.
- ~ If applicable, verify that the RHC has a current state or local license – this may be done prior to the survey. If not verified independently prior to the survey, ask to see the RHC's license while on-site.
- ~ If the surveyor identifies a situation that suggests the RHC may not be in compliance with any State or local licensure law, the information should be referred to the appropriate licensing authority for follow-up.

Survey Procedure § 491.4(b)

- ~ Verify that RHC staff and personnel are licensed, certified, or registered, as applicable.
- ~ Verify that the RHC has established, and follows procedures for determining that personnel are properly licensed, certified, and/or permitted.
- ~ Verify that the RHC has established, and implements, policies and procedures to verify that personnel working at the RHC under contract or arrangement hold whatever license, registration, or certification is required under State law.
- ~ Review a sample of personnel files of clinical staff to verify that licensure or other required credential information is present and up to date.

Survey Procedure § 491.5(a)(1), § 491.5(c) & § 491.5(d)

~ Prior to conducting an initial on-site survey, make a preliminary assessment as to whether the RHC applicant meets the basic location requirements by reviewing the Form CMS-29 Verification of Clinic Data – Rural Health Clinic Program.

~ Verify, once on-site, that the location listed on the Form CMS-29 is the same as the location where services are actually being provided.

Survey Procedures § 491.5(a)(3)(i)-(ii)

~ Determine whether the RHC has available in its permanent structure or mobile unit all of the objects, equipment, and supplies required for the provision of RHC clinical services.

~ If the RHC is a mobile unit, or has a mobile unit in addition to its permanent structure, determine whether it has a publicly available schedule for the upcoming times and locations of mobile RHC services. Determine whether the RHC has posted schedules on the unit as well as provided public notice by other means.

~ Determine whether the mobile location(s) meet the rural and shortage locations requirements.

Survey Procedures § 491.5(a)(3)(iii)

~ If the RHC has a webpage, check to see if the RHC holds itself out to the public as having multiple permanent locations.

~ Ask RHC staff members whether the RHC has any other locations, other than mobile units.

Survey Procedures § 491.6(a)

~ Observe whether the clinic's physical plant is well constructed and arranged, and does not present barriers to patient access or hazards to patient safety.

~ Observe whether the clinic has sufficient space given for the type and scope of services provided and the number of patients served.

Survey Procedures § 491.6(b)(1)

~ Is there documentation that mechanical or electrical equipment is regularly inspected, tested and maintained in accordance with the manufacturer's recommendations?

~ If documentation is missing, ask to see the clinic's policies and procedures for equipment maintenance, to determine whether the problem is with content of the policies and procedures, and or with failure to follow policies and procedures.

~ Ask staff to provide a copy of or access to copies of the manufacturer's recommendations for mechanical or electrical equipment.

~ Ask staff whether there have been any problems with equipment breakdowns or malfunctions. If yes, ask for maintenance documentation for the equipment in question.

Survey Procedures § 491.6(b)(2)

~ Verify drugs are stored according to manufacturer instructions.

~ Verify that drugs are not accessible to unauthorized individuals/personnel.

Survey Procedures § 491.6(b)(3)

~ As a resource, applicable questions from Part 2 of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM, may be used to assist with identifying the types of observations surveyors should make in an RHC with respect to hand hygiene, injection practices, and when applicable, single-use devices, high-level disinfection and point-of-care devices. This form may be used to assist RHC surveyors; however, it is not a required RHC form.

~ Observe whether all areas which patients use or in which they may receive clinic services are clean and orderly, including the waiting area(s), the exam room(s), office space, rest rooms, floors, horizontal surfaces, patient equipment, mechanical rooms, central supply, and storage areas, etc.

Survey Procedures §§ 491.7(a)(1) & 491.7(b)(3)

~ Verify that the clinic has documentation identifying the name and address of its medical director.

~ Confirm that the individual identified in the documentation is an MD or DO and still practicing at the RHC.

~ Confirm that the medical director holds a current license issued or recognized by the State where the clinic is located. Ask staff who the clinic's medical director is and confirm that the same individual is the one the RHC disclosed as its medical director.

~ If an already certified RHC clinic has no permanent medical director at the time of the survey, ask for documentation of when the previous medical director ceased performing that function, and of the efforts the RHC has made to fulfill the requirement.

Survey Procedures § 491.7(a)(2) & § 491.7(b)(1)-(2)

~ Ask the clinic to provide a copy of its organizational chart and any supporting documentation that articulates the lines of authority and responsibilities of clinic officers and personnel.

~ Ask the clinic to identify the person who is principally responsible for day-to-day operations.

~ Ask to see the clinic's current administrative and clinical policies. Do not review the content of these policies; just confirm that the clinic has written policies.

~ Verify the clinic owner as captured on the CMS-29.

~ Verify the names and addresses of the required disclosures are available in the RHCs written records.

Survey Procedures § 491.8(a)(1) & (2)

~ Confirm that the clinic has at least one physician who is providing physician services. Confirm that the physician has a current license issued or recognized by the State in which the RHC is located.

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.

Survey Procedures § 491.8(a)(3)

~ 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.

Survey Process § 491.8(a)(4)

~ Determine whether all clinical staff members who are not practitioners have a current State license or certification, as required.

~ Ask clinical staff members who are not practitioners to identify their supervisor(s)

~ Is there someone responsible for supervising non-practitioners on the clinical staff at all times the RHC is providing services? Request the name of that individual. Interview other clinical staff to confirm.

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.

Survey Procedures § 491.8(a)(6)

~ Determine what the clinic's total hours of operation are, starting with its weekly schedule. Review hours listed on signs, the RHC's website, if it has one, etc., to determine what the hours of operation are. If the RHC's schedule varies from week to week, review the schedule for a one month period.

~ Review staffing schedules for any NPs, Pas, or CNMs on the clinic's staff for the previous two months, as well as their upcoming schedule for the next month.

~ Verify that the total scheduled hours for these types of practitioners are at least 50 percent of the total hours the RHC is open.

~ Spot check a few clinical records to confirm that the practitioner was actually on-site and seeing patients on several of the days where they were listed as present on the staff schedule.

~ Review physician's schedule to assist in verifying that the required medical personnel are on site at all times the RHC is open and operating.

Survey Procedures § 491.8(b)(1) & (3)

~ Ask the clinic's medical director how he or she provides overall medical direction and supervision for the clinic.

~ Review a sample of pertinent clinic records. Is there evidence in the sample of clinical records reviewed that a physician provided assessment, diagnosis, or treatment services and/or wrote orders for patient testing and/or care?

Survey Procedures § 491.8(b)(3) & (c)(1)(ii)

- ~ Ask the clinic's staff what its policy is for the interval at which clinical records will be periodically reviewed. Ask when the last review took place, and request documentation of the review.
- ~ If State law requires co-signature of NP and/or PA orders by a physician, is there evidence in the clinical record of such co-signatures?
- ~ If the RHC has more than one physician, ask whether its policy permits physicians to share the responsibility for the periodic record review.
- ~ Ask how the RHC ensures that all records of patients cared for by non-physician practitioners are periodically reviewed.
- ~ Is there documentation supporting that the required reviews have occurred?

Survey Procedures § 491.8(c)(2)

- ~ Ask the RHC's owner, or person in charge of operations for the RHC's policies governing which services may be provided by an NP or PA, whether there are any RHC services that are outside the scope of practice of an NP or PA.
- ~ Interview NPs and/or PAs about the services they provide. If the RHC provides services that are outside their scope of practice, ask what they do if a patient requires such services when no MD or DO is available.
- ~ Verify how new practitioners are made aware of the clinic's patient care policies.
- ~ Ask to review medical records of patients who have been referred to health care services outside of the clinic. Confirm that an MD, DO, NP, or PA arranged for the referral. Is there evidence that appropriate portions of the patient's RHC record were transferred?
- ~ Review patient care records for patients being treated by and NP or PA. Do the NP or PA make entries into the record documenting the care they provide? Were the patient's health records appropriately maintained, and were those records transferred with the referred patient?

Survey Procedures § 491.9(a)(2) & (c)(1)

- ~ Review the clinic's website, and ask the clinic director to describe the types of services the clinic offers. Does it include specialty services that are not RHC services? If yes:
- ~ Review the hours the specialty services are available and the hours RHC services are available, to determine whether the majority of time the RHC provides RHC services.
- ~ Review a sample of patient health records covering at least the two previous months to determine the majority of specific services actually furnished.

Survey Procedures § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

- ~ Review meeting minutes or other documentation to verify that the required types of practitioners actually participated at least biennially in developing the policies and recommending policies to the RHC's leadership.
- ~ Ask the RHC's leadership if it ever rejects the advice of the practitioners. If yes, how does it ensure that any changes made are clinically appropriate? Does it document the rationale for its rejection of the advice? Is there documentation of the policies recommended by the practitioners as well as of any changes made by the RHC's leadership?

Survey Procedures § 491.9(b)(3)(i) & (ii)

- ~ Ask the RHC to provide a copy of its description of services. Is it consistent with services advertised on the RHC's website or via other media?
- ~ Ask the RHC's medical director to show one or more medical management guidelines and explain their source/how they were developed, as well as how they are used. Do the examples include the required elements?
- ~ Ask one or more RHC practitioners to demonstrate how they access the RHC's medical management policies. Are they familiar with the guidelines applicable to their practice?

Survey Procedures § 491.9(b)(3)(iii)

- ~ Are drugs and biologicals stored in a secure manner?
- ~ Are drugs stored in areas not accessible to unauthorized personnel?
- ~ When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?
- ~ Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- ~ When applicable, determine if the RHC has a system that tracks movement of all scheduled drugs from the point of entry into the RHC to the point of departure, either through administration to the patient, destruction of the drug, or return to the manufacturer.
- ~ Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?
- ~ Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the RHC to reconcile and address the discrepancies?
- ~ Interview the person responsible for drug storage as well as other RHC staff to determine their understanding of the RHC's controlled drug policies.
- ~ If the RHC uses CSPs and obtains them from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?
- ~ Spot-check to identify if expired or unusable medications, including when applicable medications that are past their BUD, are being used for patient care in the RHC.
- ~ Ask what type of personnel administer drugs and biologicals within the RHC, including, if applicable, IVs. Are they practicing within their permitted scope?
- ~ Observe medication administration to verify whether staff members confirm the "5 rights" of medication administration, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the RHC's policies and procedures?

Survey Procedures § 491.9(a)(3) & (c)(2)

- ~ Verify that the RHC offers the 6 required basic laboratory services on site. If it does not, is there a State law that prevents the RHC from doing so?

~ Verify that all laboratory services are operating under a current, appropriate CLIA certificate, including for additional services provided in the RHC beyond the minimum required 6 basic laboratory services.

Survey Procedures § 491.9(c)(3)

~ Review the RHC's written policies and procedures to determine the types and quantities of drugs/biologicals it stores for medical emergency purposes.

~ Review all of the drugs/biologicals that are stored and available in the RHC, including in what quantities, to verify the RHC maintains a supply of commonly used drugs and biologicals adequate to handle the volume and type of medical emergencies it typically encounters.

~ Ask RHC staff how they determine the quantity and specific types of drugs and biologicals to have on hand. How do they ensure that the specified drugs and biologicals are on hand in the quantities specified per RHC policy and have not expired?

~ Any findings as a result of the inquiry, may lead to noncompliance under 42 CFR 491.9(b).

Survey Procedures § 491.9(d)

~ Determine whether the RHC has referral arrangements with at least one of each of the specified types of providers and suppliers.

~ If the referral agreements are not in writing, ask the RHC for evidence that referred patients are being accepted for treatment.

Survey Procedures §491.10(a)(1)-(2)

~ Verify that the RHC has written policies and procedures governing its clinical record system.

~ Do not review the policies and procedures unless observations, interviews or record reviews indicate noncompliance with the requirements of the Clinical Records Condition. At that time, ask to review the pertinent policies and procedures to determine whether the noncompliance is based on deficient policies or based upon failure to implement compliance policies.

~ Verify a professional staff member has been designated responsible for the RHC's clinical record system.

~ Ask the responsible individual whether there have been changes in the system, e.g., adoption of a partial or full EHR system, and, if so, for evidence that the RHC's policies and procedures were updated to reflect the clinical record system currently in use.

~ If the RHC has an EHR system, immediately after the entrance conference interview, ask the person who is responsible for the RHC's clinical record system to give an overview of the EHR system, including:

~ Whether there is one system that is fully integrated throughout the RHC or a hybrid EHR-paper record system. In the case of a hybrid system, have the RHC identify which parts of the RHC use which systems. Ask how the RHC ensures that the clinical record is complete, accurate, and accessible in this hybrid environment;

~ What the arrangements are in the event of an EHR system failure, to ensure that complete and accurate medical records are accessible;

- ~ Observe how staff members use the EHR system to determine whether they are able to access complete clinical record information when needed. When applicable, observe whether or not staff members make entries promptly.
- ~ If the RHC shares an EHR system with other providers, is the RHC able to demonstrate that the RHC's clinical records are readily identifiable, distinguishable from other information in the shared system and accessible by appropriate RHC staff members only?
- ~ If the RHC uses a partial or whole paper clinical record system, are records legible?
- ~ When reviewing sampled clinical records is there evidence that any of the records are inaccurate or incomplete?
- ~ Is each entry dated, timed, and authenticated?
- ~ If RHC policy permits authorized individuals to make entries on behalf of a practitioner, has the practitioner promptly authenticated the entry?
- ~ Is each clinical record systematically organized?
- ~ Are the medical records organized in a systematic manner allowing easy retrieval?

Survey Procedures § 491.10(a)(3)(i) – (iv)

- ~ Determine whether there is a medical history for each RHC patient whose clinical record is reviewed. Is there evidence that a practitioner reviewed the medical history?
- ~ Ask the RHC what its policy is for updating a patient's medical history; ask for documentation of the policy.
- ~ When applicable, determine if clinical records in the sample being reviewed include an updated medical history.
- ~ Determine whether the RHC has adopted policies and procedures addressing when an informed consent is required.
- ~ Determine whether there is an informed consent when required in the medical record, and that it contains the minimum required elements as well as any additional elements required under RHC policy
- ~ In records reviewed, is there evidence of:
 - ~ The practitioner's assessment of the patient's health status and health care needs?
 - ~ A documented summary of the visit, including the required regulatory information?
 - ~ Physical examination findings, diagnostic and laboratory test results, and consultative findings
 - ~ Are findings and test reports appropriately authenticated by a practitioner?

Survey Procedures §491.10(b)

- ~ Verify that only authorized persons are permitted access to clinical records
- ~ Observe the RHC's security practices for patient records. Are paper clinical records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, or on counters where an unauthorized person could gain access to patient records?
- ~ Verify that precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

~ Verify that the RHC has policies and procedures governing disclosure of clinical record information, including when the patient's written consent is required.

Survey Procedures § 491.11 (a) - (c)

~ Is there evidence that the evaluation is completed at least biennially and includes review of the number of patients served and the volume of services provided?

~ Is there evidence of a review of a representative sample of RHC records?

~ Does the sample include the required minimum number of records?

~ Who conducts which portions of the review? Are they qualified to do so?

~ Is there evidence of findings and recommendations from the review, and do the findings address each required component?

Survey Procedures § 491.11(d)

~ Does the RHC have documentation of leadership review of the evaluation findings each year?

~ Is there evidence of the RHC taking corrective actions?

~ If the RHC did not take recommended corrective actions or took corrective actions different from those recommended, did it document an appropriate rationale supporting its decision?