



RHC Inspection Checklist – Survey Procedures

The Rural Health Clinic (RHC) statutory provisions are set forth in Section 1861(aa) of the Social Security Act (the “Act”). Specifically, Section 1861(aa)(2)(K) of the Act requires Medicare participating RHCs to meet other requirements as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services at the RHC. In accordance with 42 CFR §405.2402, RHCs are required to be certified as in compliance with the Medicare Conditions for Certification (CfC) at 42 CFR Part 491, Subpart A in order to enroll in the Medicare program. The following bullet points from the Interpretative Guidelines for RHCs issued in January 2018 are the source for these procedures. Here is the link:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

Credentialing 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.
- Review a sample of personnel files of clinical staff to verify that licensure or other required credential information is present and up to date.

Medical Director 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 and has at least one patient visit per year.

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



Preventive Maintenance Interpretative Guidelines

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

Physical Plant 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.

Preventive Maintenance 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.



Drugs and Medications -Interpretative Guidelines § 491.6(b)(2)

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

Drugs and Medications Survey Procedures § 491.6(b)(2)

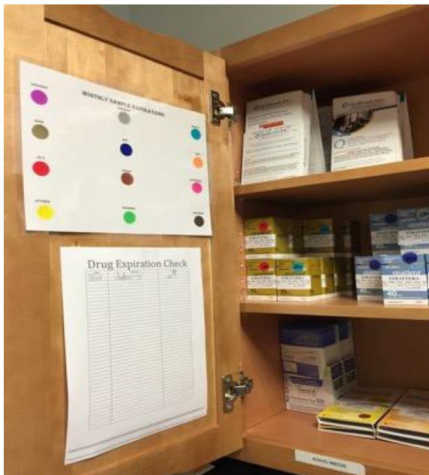
- Verify drugs are stored according to manufacturer instructions.
- Verify that drugs are not accessible to unauthorized individuals/personnel.

Survey Procedures § 491.9(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?

Medication Storage



Secured/Organized In Original Containers, Not Expired/Past BUD, No MDV in Immediate Treatment Areas, SDV contents Not Saved



Laboratory

The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

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

Interpretative Guidelines § 491.9(a)(3) & (c)(2)

Basic laboratory services must be provided in the RHC by RHC staff in order to facilitate the immediate diagnosis and treatment of the patient. To the extent permitted under State and local law, the 6 basic laboratory services listed in § 491(c)(2) are considered the minimum laboratory services the RHC must have available within the clinic, provided by RHC staff. If any of these laboratory services cannot be provided at the RHC due to a State or local law prohibition, that laboratory service is not required for Medicare certification. These laboratory services must be provided in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR Part 493 operating under a current CLIA certificate appropriate to the level of services performed. However, compliance with CLIA requirements is not assessed by surveyors conducting RHC surveys. Surveyors should, however, ask to see the RHC's CLIA certificate. RHCs may also provide additional laboratory services, either on-site or through an offsite arrangement, but if it does so, these optional services must also comply with the CLIA requirements. For example, an RHC may have an arrangement with some other provider of clinical laboratory services. However, such arrangements are not permitted to substitute for the requirement to actually provide the 6 basic laboratory services within the RHC, by RHC staff.

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.

Top 10 Infection Control Tips for Facilities Managers



Cleanliness -Interpretative Guidelines § 491.6(b)(3)

The RHC must provide and maintain a clean and orderly environment. All areas of the clinic must be clean. These areas include, but are not limited to, the waiting area(s), exam room(s), staff lunch room(s), rest room(s), and office space. The clinic must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and clean environment.

Policies and procedures for an orderly and clean environment must address the following:

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

As a resource, applicable questions from Part 2 of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf , 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.



First Response to a Medical Emergency

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

Interpretative Guidelines § 491.9(c)(3)

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

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

It is appropriate for a RHC to store a small volume of a particular drug/biological, if it generally handles only a small volume/type of a specific emergency.

Survey Procedures § 491.9(c)(3)

- Verify that the RHC has drugs or biologicals in each of the listed categories on hand for emergencies.
- 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?



NP/PA 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.

Hours of Operation - 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.

Ancillary Personnel - Interpretative Guidelines § 491.8(a)(4)

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

Ancillary Personnel -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.



Staffing - 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.

Licensed Providers and Staff

Licensed Staff Member	State of Origin License # (or Certificate #)	Expiration Date	DEA Certificate # (as applicable)	Expiration Date	BLS Exp For Licensed and Certified Patient Care Personnel	Verification & copies of professional license, registration and/or certification is maintained if applicable.



Medical Director 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?

The Medical Director of the Rural Health Clinic should do the following:

- a. Supervise and collaborate with the Nurse Practitioner/ Physician Assistant in accordance with State scope of practice regulations in the state.
- b. Review and sign Nurse Practitioner/Physician Assistant protocols with the NP/PA provider on an annual basis.
- c. Review at least 15 charts per Nurse Practitioner/ Physician Assistant per quarter, communicate those results to the Nurse Practitioner/ Physician Assistant and sign the document that indicates the review took place. Review both active and closed charts. See Examples of Chart Audit Forms.
- d. Participate in the Clinic's needs assessment, quality assurance, utilization review and peer review programs.
- e. Review the RHC Policy and Procedure manual on an annual basis and sign the signature page indicating the review took place.
- f. Participate and review the annual evaluation or program evaluation process and sign the signature page indicating participation.
- g. Review and participate in the development in policies, procedures, training, and drills regarding emergency preparedness especially related to medical emergencies and the proper procedures to be followed in case of a medical emergency and provide guidance on the types of emergency drugs to be maintained at the rural health clinic.

Medical Director - Interpretative Guidelines § 491.8(b)(3) & (c)(1)(ii)

A physician must review periodically the RHC's patient clinical records. In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, an RHC physician must review and sign all such records. If there is more than one physician on the RHC's staff, it is permissible for staff physicians other than/in addition to the medical director to review and co-sign the records.

The RHC's NP(s) and/or PA(s) must participate in the physician's review of the clinical records. Participation may be face-to-face or via telecommunications. If there is more than one NP or PA in the clinic, the NP or PA would participate only in the review of records of those patients for which the NP or PA provided care. Where co-signature is not required, the regulation still requires periodic physician review of the clinical records of patients cared for by non-physician practitioners. If the RHC has more than one physician on its staff, it is permissible for physicians other than/in addition to the medical director to conduct the periodic review of clinical records, so that this task might be divided or shared among the physicians.

If the RHC has more than one physician, its policies and procedures must specify who is authorized (i.e. whether it is the medical director alone, or may include other staff physicians) to review and, if required under State law, co-sign clinical records of patients cared for by a non-physician practitioner. The regulation does not specify a particular timeframe to satisfy the requirement for "periodic" review of clinical records, but the RHC must specify a maximum interval between record reviews in its policies and procedures. The RHC is expected to take into account the volume and types of services it offers in developing its policy. For example, an RHC that has office hours only one day per week would likely establish a different requirement for record review than an RHC that is open 6 days per week/ 10 hours per day.

Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the RHC has electronic clinical records that can be accessed and digitally signed remotely by the physician, this method of review is acceptable. Therefore, RHCs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

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?

REFERRAL



Referrals - Interpretative Guidelines § 491.8(c)(2)

The NP or PA must perform the following functions if they are not being performed by a physician:

- Providing health care services in accordance with the RHC's written policies. However, non-physician practitioners must also operate within their State-permitted scope of practice and may not provide clinic services that require a broader scope of practice;
- Arranging for or referring patients to services which cannot be provided at the RHC; and
- Ensuring that adequate patient health records are maintained. If a patient is referred for additional treatment elsewhere, the NP or PA must ensure that the records are transferred.

Referrals - Survey Procedures § 491.8(c)(2)

- Ask the RHC for the RHC's policies governing which services may be provided by an NP/PA, whether there are any RHC services that are outside the scope of practice of an NP/PA.
- Interview NPs/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?

Interpretative Guidelines § 491.9(d)

The clinic has referral agreements with at least one Medicare/Medicaid-participating:

- Hospital or CAH, for inpatient acute care;
- Physician;
- Diagnostic testing facility (which could be a hospital or CAH or a freestanding diagnostic testing facility) for ambulatory diagnostic tests not furnished in the RHC; and
- Clinical laboratory, for laboratory services not furnished in the RHC.

The referral arrangements do not have to be in writing, but if they are not there must be evidence that RHC patients referred for additional services are being accepted and treated by the provider/supplier they are referred to.

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.



Provision of Services - Interpretative Guidelines § 491.9(a)(2) & (c)(1)

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

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

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

Provision of Services - 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.



Policies and Procedures-Interpretative Guidelines § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

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

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

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 annually 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?

Patient Care Policies - Interpretative Guidelines § 491.9(b)(3)(i) & (ii)

The written RHC patient care policies must include:

Description of Services: The written policies must provide a description of the services the RHC furnishes, whether directly using RHC staff or through an agreement or arrangement. The services furnished by the clinic must be described in sufficient detail to permit understanding of the scope of all services furnished in the RHC, and the scope/type of agreement or arrangement they are furnished through if applicable. An example of services under arrangement might be provision by a contractor of additional laboratory services beyond those required to be performed by RHC staff. Such statements as the following may sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning. Statements such as "complete management of common acute and chronic health problems" standing alone, would not sufficiently describe services.

Guidelines for Medical Management The clinic's written guidelines for the medical management of health problems include a description of the scope of medical care that may be furnished by a PA, NP, or CNM, including the extent and nature of required supervision. The guidelines would also include standard protocols for diagnosis and treatment of common conditions or for provision of preventive care. Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self limiting health problems, and medical emergencies. The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition; its etiology; its clinical features; recommended laboratory studies; differential diagnosis, treatment procedures, complications, consultation/referral required; and follow-up. Guidelines also may be based on guidelines of nationally recognized professional organizations, which are referenced and reproduced, such as the immunization guidelines developed by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. However, the guidelines must include information on actions non-physician practitioners in the RHC are permitted to take, as well as circumstances warranting referral.

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

- Be comprehensive enough to cover most health issues covered in a primary and preventive care setting;
- Describe the actions a NP, PA or CNM may initiate or implement, consistent with State scope of practice requirements; and
- Describe the circumstances that require consultation with the RHC's MD or DO, as well as external referral. Guidelines may be in electronic or paper format, but should be readily accessible to RHC practitioners, all of whom must be familiar with them.

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?



Interpretative Guidelines § 491.10(a)(1)-(2)

The RHC must maintain a complete, comprehensive and accurate clinical record (also referred to as a medical record) for each RHC patient. The RHC must use the information contained in each clinical record in order to ensure the delivery of appropriate care to each RHC patient. The RHC must have a designated member of its professional staff (which may be an administrative professional rather than a clinical professional) who is responsible for the RHC's clinical record system. That individual is responsible for developing and implementing, with approval of the RHC's professional staff and leadership, written clinical record policies and procedures.

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

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

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.

Here is a sample Chart Audit Form that should be used each quarter to record medical record reviews.

Patient Health Records

Medical Record Audit Tool Insert "Y" (YES) if evidence is found, "N" (NO) if evidence of is missing, or "NA" if not applicable. Insert an "M" next the patient number if the patient is a minor child.								
Patient	Patient ID & Social Data	Written Consent to Treat	Medical History	Health Status & Patient Health Needs	Summary & Patient Instructions	Labs Diagnostics & Consult Info	Physicians' Orders & Treatments & Medications (includes allergies)	Signature of Provider & Date
1.								
2.								
3.								
4.								



Program Evaluation

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

(b) The evaluation includes review of:

- (1) The utilization of clinic . . . services, including at least the number of patients served and the volume of services;
- (2) A representative sample of both active and closed clinical records; and
- (3) The clinic’s . . . health care policies.

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

- (1) The utilization of services was appropriate;
- (2) The established policies were followed; and
- (3) Any changes are needed.

Interpretative Guidelines §491.11(a)-(c)

The RHC is required to conduct an evaluation of its total clinical program, at least annually. This evaluation may be done by RHC staff or through arrangement with other appropriate professionals. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so.

The evaluation must include, at a minimum, the number of patients served and the volume of services provided. The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population. It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted. The evaluation does not have to be done all at once or by the same individuals. However, if the evaluation is not performed all at once, no more than one year may elapse between evaluating the same components.

A RHC that has been certified for less than one year may not have done a program evaluation. However, the RHC must have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered within the evaluation.

The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC’s current patients or 50 records, whichever is less. The purpose of the review is to determine whether utilization of the RHC’s services was appropriate, i.e., whether practitioners adhere to accepted standards of practice and adhere to the RHC’s guidelines for medical management when diagnosing or treating patients. The review also

must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies. The evaluation of practitioners must be conducted by an MD or DO; if there is only one MD or DO practicing in the RHC, it is expected that the RHC will arrange for an outside MD/DO to review the selected sample of records of RHC patients cared for by the RHC's MD/DO. The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.

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

Annual Evaluation - Survey Procedures § 491.11(a)-(c)

- Does the RHC have documentation that its clinical program is reviewed at least annually?
- Is there evidence that the evaluation 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?

For More Information

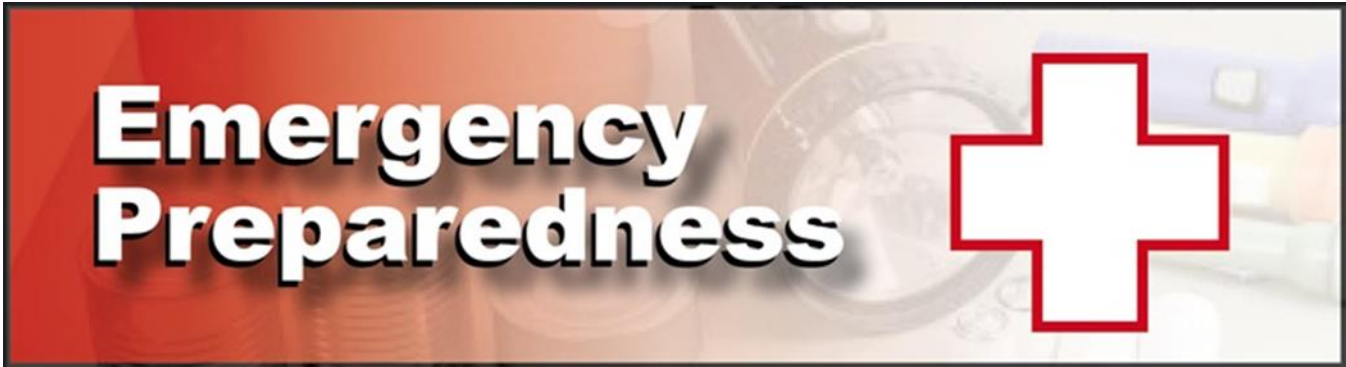
For additional Resources contact Mark Lynn at (423) 243-6185 or marklynnrhc@gmail.com or go to:

- <http://www.ruralhealthclinic.com/certification-materials>
- <http://www.ruralhealthclinic.com/resources/>

For Recordings of our webinars, go to https://www.youtube.com/channel/UCXW4pkwNzDXVTMFrFwMy2_A and subscribe to our YouTube Channel.

Please join our Facebook Group which currently has over 550 members. This is where we post updated RHC information, resources and files to use in managing your rural health clinic, announcements of Technical Assistance webinars, HBS webinars, and HBS seminars.

<https://www.facebook.com/groups/1503414633296362/>



The **Centers for Medicare & Medicaid Services (CMS)** requires **Rural Health Clinics** to be in compliance with **all components** of the Emergency Preparedness final rule: **42 CFR Part 491.12**. These components **include but are not limited to** the following:

Risk assessment and emergency planning: An “all-hazards” risk assessment was performed, and essential components of this assessment have been integrated into the emergency preparedness plan and planning.

1. _____ **Date the most recent “all hazards” assessment was performed or updated.**
2. _____ **Date the most recent review (revision, if applicable) of the emergency plan.**

Policies and Procedures: The facility has developed Policies and Procedures to promote and support the successful outcome of the emergency plan.

3. _____ **Date the most recent review (revision, if applicable) of the Emergency Policies and Procedures.**

Communication Plan: The facility has developed and maintains a comprehensive emergency preparedness communication plan. The communication plan is fully coordinated within the facility, with state and local emergency management agencies, and with other healthcare providers as necessary.

4. _____ **Date the most recent review (revision, if applicable) of the Communication Plan.**

Training and Testing: The facility developed and maintains a training and testing program for emergency preparedness. The program includes initial training of staff and involves personnel as well as refresher courses, drills and exercises. The program includes methods to identify areas of the plan that need improvement and the processes and procedures to enact those improvements. *Dates within this section may only be used once and must be within the previous 12 calendar months. To be considered compliant, providers must submit two test dates or one test date along with a date the facility emergency plan was activated.*

5. _____ **and** _____ **Dates of the most recent tests.**

6. _____ **Date of the most recent training of staff on Emergency Preparedness**

Contact with Local EMA Official regarding of Emergency Preparedness: The facility is knowledgeable of how to contact the local EMA Director and has consulted with them regarding the content of their emergency preparedness plans.

7. _____ **Date of the most recent contact with local EMA Director.**

For Resources to complete the Emergency Preparedness Process contact Mark Lynn at marklynnrhc@gmail.com or go to <http://www.ruralhealthclinic.com/emergency-preparedness>.