North Dakota Rural Health Clinic Conditions for Certification Checklist

Created June 2023



Funded By:

North Dakota Medicare Rural Hospital Flexibility Program
Federal Office of Rural Health Policy
Health Resources and Services Administration
U.S. Department of Health and Human Services



Important:

The contents of this Conditions for Certification checklist reflect the opinion of the North Dakota Rural Health Clinic (ND RHC) Network only. This publication is for informational purposes. It is meant to be a tool to assist ND RHC Network members with the Centers for Medicare and Medicaid (CMS) State Operations Manual – Appendix G and Appendix Z.

The Conditions for Certification checklist is not inclusive, and the specific tag and licensing references should be reviewed to ensure each RHC understands and complies with all parts of the regulation/rules. Please use the checklist in conjunction with other resources. Other regulations may also apply that are not included in this documents (i.e., Pharmacy, Life Safety Codes). The ND RHC Network is not able to ensure that this document is current at all times as changes do occur on occasion.

Survey Preparation Suggestions

1. Ensure that all staff understand their role in the survey process and continue checking for compliance on a regular basis.

2. Gather necessary and preferred documentation (ensure that everything is

current).

| Floor plan |
| Organizational chart |
| List of staff and roles |
| Hours of operation |
| List of services including any that may be contracted |
| Quality assurance/quality improvement plans |
| Infection control plan |
| Network agreements |
| Copy of current CLIA |
| Current policy and procedure manual

Documentation of clinic ownership

Rural Health Clinic (RHC) Survey Information Request

<u>Upon</u>	surveyor arrival:
	Provide a list of Visiting Nurse Service (VNS) visits scheduled during the
	survey period (if any scheduled, one visit will be observed)
	Provide a list of names, locations, and telephone numbers of key RHC
	staff and their responsibilities
	Provide a list of patients scheduled for the day of survey
	Provide a list of all office visits for the past six months
	Provide a list of all (if any) patients transferred to another facility for
	emergency services
Withi	n one hour of request:
	Provide a location (conference room; empty office) for the surveyor to
	review patient records/conduct interviews
	Provide access to a copy machine (if needed)
	Provide a list of all staff including the medical director, active medical
	staff, support staff, and any staff providing patient care
	Provide a copy of the organizational chart
	Provide any policies or procedures, upon request
	Provide selected RHC personnel records
	Provide documentation of the RHC's program evaluation or Quality
	Assurance and Performance Improvement (QAPI) for ongoing self-
	assessment of quality
	Provide a list of services provided through agreement or arrangements
	Provide a copy of the facility's floor plan

Notes:			

REQUIREMENT

PURPOSE AND SCOPE (491.1)

☐ The clinic meets the purpose and scope of regulations in order to meet reimbursement requirements for Medicare and Medicaid

DEFINITIONS (491.2)

Unless the context indicates otherwise:

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

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the state, who meets the state's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

- a. Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or
- b. Has satisfactorily completed a formal one academic year educational program that:
 - Prepares registered nurses to perform an expanded role in the delivery of primary care;
 - ii. Includes at least four 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
 - iv. 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 (b) 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 means the following:

- As it pertains to the supervision, collaboration, and oversight requirements, a Doctor of Medicine or osteopathy legally authorized to practice medicine or surgery in the state in which the function is performed; and
- b. Within limitations as to the specific services furnished, a Doctor of Dental Surgery or of dental medicine, a Doctor of Optometry, a Doctor of Podiatry or surgical chiropody or a chiropractor.

REQUIREMENT

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:

- a. Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or
- b. Has satisfactorily completed a program for preparing physician's assistants that:
 - i. Was at least one academic year in length;
 - ii. Consisted of supervised clinical practice and at least four months (in the aggregate) of classroom instruction directed toward preparing students to deliver healthcare; and
 - iii. Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or
- c. Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements under (b) 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.

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

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

TAG	REQUIREMENT
	CERTIFICATION PROCEDURES (491.3)
J-0001	 A Rural Health Clinic will be certified for participation in Medicare. a. The secretary will notify the state Medicaid agency whenever he or she has certified or denied certification under Medicare for a prospective rural health clinic in that state. b. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.
J-0002	 Physician's services are professional services that are furnished by either of the following: a. By a physician at the RHC. b. Outside of the RHC by a physician whose agreement with the RHC provides that he or she will be paid by the RHC for such services and certification and cost reporting requirements are met.
J-0003	Visiting Nurse Services are covered if the services meet the following:
	 The RHC is located in an area in which the secretary has determined there is a shortage of home health agencies. The services are rendered to a homebound individual. The services are furnished by a registered professional nurse or licensed practical nurse that is employed by or receives compensation for the services from the RHC. The services are furnished under a written plan of treatment that is both of the following: a. Established and reviewed at least every 60 days by a supervising physician of the RHC; OR b. Established by a nurse practitioner, physician assistant or certified nurse midwife; AND

TAG REQUIREMENT J-0003 □ Nursing care that is covered includes the following: a. Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved. b. Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications. c. This benefit does not cover household and housekeeping services or other services that would constitute custodial care. **Homebound** means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. "Place of residence" does not include a hospital or long-term care facility. Visiting Nurse Services: Determination of shortage of agencies: ☐ A shortage of home health agencies exists if the secretary determines that the RHC: a. Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC. b. Has (or expects to have) patients whose permanent residences are not within the area services by a participating home health agency. c. Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency. RHCs are permitted to offer Visiting Nurse Services (VNS) in patients' homes if they are located in an area with a shortage of home health agencies.

TAG	REQUIREMENT
J-0003	☐ To provide VNS, the RHC must apply to the State Agency, which
	performs an assessment in accordance with regulations. Based on this
	assessment, the State Agency makes a recommendation to the CMS
	Regional Office (RO), and the RO makes the determination whether the
	RHC will be permitted to offer VNS.
	☐ If an RHC provides VNS, the State Agency must confirm that the services are being provided:
	a. By a registered nurse (RN) or a licensed practical nurse (LPN) who
	is employed by or receives compensation from the RHC for
	providing such services.
	b. In accordance with a written plan of treatment which is:
	established and signed by a supervising RHC physician, nurse
	practitioner, physician assistant, or certified nurse midwife.
	c. Reviewed and signed at least every 60 days by the supervising
	RHC physician.
	d. Identifies the nursing and personal care services that are to be
	provided to the individual.
	☐ The VNS must be provided in the patient's home and must be
	documented in the RHC's clinical records, in accordance with regulatory requirements.
J-0003	☐ For survey purposes, the surveyor will:
7 0003	a. Review personnel files of staff making VNS visits, to ensure that
	they are currently licensed as either an RN or an LPN.
	b. Review a sample of records of patients receiving VNS to
	determine:
	c. Ensure there is a written treatment plan for each patient,
	established and signed by an RHC physician or non-physician
	practitioner;
	d. Ensure there is evidence that the plan was reviewed by an RHC
	physician at least every 60 days;
	e. Ensure the clinical record documents the provision of VNS to the patient in accordance with the written plan for that patient.
	f. 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.

TAG	REQUIREMENT
	COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS (491.4)
J-0010 J-0011	The Rural Health Clinic (RHC) and its staff are in compliance with applicable federal, state, and local laws and regulations.
J-0012	☐ The clinic is licensed pursuant to applicable state and local law.
J-0013	 Staff of the clinic are licensed, certified, or registered in accordance with applicable state and local laws.

TAG	REQUIREMENT
	LOCATION OF CLINIC (491.5)
J-0020 J-0021	
	designated by the Census Bureau as urban. c. Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural. Criteria for designation of shortage areas. a. The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are: i. The ratio of primary care physicians practicing within the area to the resident population. ii. The infant mortality rate. iii. The percent of the population 65 years of age or older. iv. The percent of the population with a family income below the poverty level.

TAG	REQUIREMENT
J-0021	The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:
	 a. The area served is a rational area for the delivery of primary medical care services.
	 b. The ratio of primary care physicians practicing within the area to the resident population.
	 c. The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.
	Medically underserved population . A medically underserved population includes the following:
	 a. A population of an urban or rural area that is designated by Public Health Services (PHS) as having a shortage of personal health services.
	☐ A population group that is designated by PHS as having a shortage of personal health services.
J-0022	 The RHC may be a permanent or mobile unit. a. 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.
	 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).
J-0023	☐ 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.

TAG	REQUIREMENT
	PHYSICAL PLANT AND ENVIRONMENT (491.6)
J-0040 J-0041	 Construction. 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.
J-0042	☐ <i>Maintenance.</i> The clinic has a preventive maintenance program to ensure that:

	a. All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition.
TAG	REQUIREMENT
J-0043	 Drugs and biologicals are appropriately stored.
J-0044	☐ The premises are clean and orderly.

TAG	REQUIREMENT
	ORGANIZATIONAL STRUCTURE (491.7)
J-0060 J-0061	 The clinic is under the medical direction of a physician and has a healthcare staff that meets the regulatory requirements. The clinic discloses the names and addresses of: Its owners, in accordance with regulatory requirements. The person principally responsible for directing the operation of the clinic. The person responsible for medical direction.
J-0062	 The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

TAG	REQUIREMENT
	STAFFING AND STAFF RESPONSIBILITIES (491.8)
J-0080	$\ \square$ The clinic has a healthcare staff that includes one or more physicians.
J-0081	$\ \square$ 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.
J-0082	 Rural Health Clinic staff must also include one or more physician's assistants or nurse practitioners.
	 At least one physician assistant or nurse practitioner must be an employee of the clinic.
J-0083	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.
J-0084	 The staff may also include ancillary personnel who are supervised by the professional staff.
J-0085	The staff is sufficient to provide the services essential to the operation of the clinic.

TAG	REQUIREMENT
J-0085	 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.
J-0086	 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.
J-0100	 The physician performs the following: a. Provides the medical direction for the clinic's healthcare activities and consultation for, and medical supervision of, the healthcare staff. b. In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinics written policies and the services provided to federal program patients.
J-0101	 Periodically reviews the clinics or centers patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.
J-0102	 The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by the physician: a. Provides services in accordance with the clinic's policies. b. Arranges for, or refers patients to, needed services that cannot be provided at the clinic. c. Assures that adequate patient health records are maintained and transferred as required when patients are referred.

TAG	REQUIREMENT
PROVISION OF SERVICES (491.9)	
J-0120	 All services offered by the clinic are furnished in accordance with applicable federal, state, and local laws.
J-0121	 The clinic's healthcare services are furnished in accordance with appropriate written policies which are consistent with applicable state law.

TAG	REQUIREMENT
J-0122	 The clinic is primarily engaged in providing outpatient health services and meets all other conditions. 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 Treatment for a variety of medical conditions
J-0123	In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinics written policies and the services provided to federal program patients.
J-0123	 The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic staff. These policies are reviewed at least every two years by the group of professional personnel identified above and reviewed as necessary by the clinic.
J-0124 J-0125	 The policies include: a. A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. b. Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of healthcare records, and procedures for the periodic review and evaluation of the services furnished by the clinic. c. Rules for the storage, handling, and administration of drugs and biologicals.

TAG	REQUIREMENT
J-0135	 The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including: a. Chemical examinations of urine by stick or tablet method or both (including urine ketones) b. Hemoglobin or hematocrit c. Blood glucose d. Examination of stool specimens for occult blood e. Pregnancy tests f. Primary culturing for transmittal to a certified laboratory
J-0136	 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: a. Analgesics b. Anesthetics (local) c. Antibiotics d. Anticonvulsants e. Antidotes and emetics f. Serums and toxoids
J-0140	 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: a. Inpatient hospital care. b. Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere) c. Additional and specialized diagnostic and laboratory services that are not available at the clinic. If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated.

TAG	REQUIREMENT
	PATIENT HEALTH RECORDS (491.10)
J-0150	☐ The clinic maintains a clinical record system in accordance with
	written policies and procedures.

TAG	REQUIREMENT
J-0151	 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.
J-0152	 For each patient receiving healthcare services, the clinic maintains a record that includes, as applicable: a. Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and healthcare needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient. b. Reports of physical examinations, diagnostic and laboratory test results, and consultative findings. c. All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress. d. Signatures of the physician or other healthcare professional.
J-0153	 The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use. Written policies and procedures govern the use and removal of records from the clinic the conditions for release of information. The patient's written consent is required for release of information not authorized to be released without such consent.
J-0154	 The records are retained for at least six years from date of last entry, and longer if required by state statute.

TAG	REQUIREMENT
	PROGRAM EVALUATION (491.11)
J-0160	☐ The clinic carries out, or arranges for, a biennial evaluation of its total
J-0161	program.
	a. The evaluation includes review of:
	i. The utilization of clinic services, including at least the number
	of patients served and the volume of services.
	ii. A representative sample of both active and closed clinical
	records.
	iii. The clinic's healthcare policies.
	b. The purpose of the evaluation is to determine whether:
	 The utilization of services was appropriate.
	ii. The established policies were followed.
	iii. Any changes are needed.
J-0162	☐ The clinic staff considers the findings of the evaluation and takes
	corrective action if necessary.

TAG	REQUIREMENT
	EMERGENCY PREPAREDNESS (491.12)
E-0001	 The Rural Health Clinic (RHC) must establish and maintain an emergency preparedness program that meets the requirements of regulation.
E-0004	 The RHC must comply with all applicable federal, state, and local emergency preparedness requirements.
E-0006	 Emergency Plan. The RHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two years. The plan must do all of the following:
	 Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. Include strategies for addressing emergency events identified by the risk assessment.
E-0007	Address patient population, including, but not limited to, the type of services the RHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
E-0009	Include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.
E-0013	 Policies and procedures. The RHC/FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan, risk assessment, and the communication plan. The policies and procedures must be reviewed and updated at least every two years.
E-0020	At a minimum, the policies and procedures must address the following: Safe evacuation from the RHC, which includes appropriate placement of exit signs, staff responsibilities, and needs of the patients.

TAG	REQUIREMENT
E-0022	 A means to shelter in place for patients, staff, and volunteers who remain in the facility.
E-0023	 A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
E-0024	The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state and federally designated healthcare professionals to address surge needs during an emergency.
E-0029 E-0030	 □ Communication plan. The RHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two years. □ The communication plan must include all of the following: a. Names and contact information for the following: i. Staff ii. Entities providing services under arrangement iii. Patients' physicians iv. Other RHCs v. Volunteers
E-0031	 Contact information for the following: a. Federal, state, tribal, regional, and local emergency preparedness staff b. Other sources of assistance
E-0032	 Primary and alternate means for communicating with the following: a. RHC staff b. Federal, State, tribal, regional, and local emergency management agencies
E-0033	 A means of providing information about the general condition and location of patients under the facility's care.
E-0034	 A means of providing information about the RHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

TAG	REQUIREMENT
E-0036	 Training and testing. The RHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan, risk assessment, policies and procedures, and the communication plan. The training and testing program must be reviewed and updated at least every two years.
E-0037	 Training Program. The RHC must do all of the following: a. Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. b. Provide emergency preparedness training at least every two years. c. Maintain documentation of the training. d. Demonstrate staff knowledge of emergency procedures.
E-0039	 Testing. The RHC must conduct exercises to test the emergency plan at least annually. a. Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every two years. If the RHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC is exempt from engaging in a community-based or individual, facility-based full-scale exercise for one year following the onset of the actual event. b. Conduct an additional exercise that may include, but is not limited to following: A second full-scale exercise that is community-based or an individual, facility-based functional exercise. A mock disaster drill. A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

TAG	REQUIREMENT
E-0039	c. Analyze the RHC response to and maintain documentation of all drills tabletop exercises, and emergency events, and revise the RHC's emergency plan, as needed.
E-0042	 □ Integrated healthcare system: If a RHC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the RHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:
	testing programs that meet the regulatory requirements.

Abbreviation	Meaning
CfC	Conditions for Certification
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
LPN	Licensed Practical Nurse
ND	North Dakota
PHSA	Public Health Service Act
QAPI	Quality Assurance and Performance Improvement
RHC	Rural Health Clinic
RN	Registered Nurse
RO	Regional Office
VNS	Visiting Nurse Service