 OREGON OFFICE OF RURAL HEALTH

# RURAL HEALTH CLINIC PRE-CERTIFICATION PRACTICE TOOL

Updated: May 2023

| **JTAG REGULATION THINGS TO LOOK FOR MEETS SPECIFICATIONS (Y/N)** | **ACTION NEEDED/COMMENTS** |
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| J11 | **§ 491.4 Compliance with Federal, State and local laws**The rural health clinic and its staff are in compliance with applicable Federal, State, and local laws and regulations. |
| J12 | **§ 491.4 (a**) Licensure of clinic or center. The clinic or center is licensed pursuant to applicable State and local law. | Compliance with this law may be observed throughout the survey (i.e., reviewing patient charts). Surveyor may refer suspected noncompliance to the appropriate Federal or State Agency, for example, blood-borne path. issues to OSHA or controlled drug accountability to the DEA.RHCs in Oregon fall under federal jurisdiction only and do not require a state license. If a CAH has a clinic that is an RHC, then the clinic is federally certified and only federal regulations apply.  |   |  |
| J13 | **§ 491.4(b) Licensure, certification or registration of personnel.** Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws. | All clinical staff must have current BLS certificates on file.This regulation relates to scope of practice and the State’s Nurse Practice Act. Oregon Nurse Practice Act is found here: <https://www.oregon.gov/osbn/Pages/laws-rules.aspx>.  Personnel files must include employee application, resume (if applicable), current license/certificate, employment forms and performance appraisal. Staff personnel files may be reviewed. Refer to the state personnel record review sheet. HCWs TB upon hire and if exposed. Hepatitis B, proof of vaccine, titer draw or declination form. |  |  |
| **J20 § 491.5 Location of Clinic** |  |
| J21 | **§ 491.5(a)(1,3)** **Basic Requirement.** The clinic is located in a rural area that is designated as a shortage area, and may be a permanent or a mobile unit. |
| J23 | **§ 491.5(a)(3)** **Permanent unit (i)** The objects, equipment and supplies necessary for the provision of the services furnished directly by the clinic are housed in a permanent structure. If clinic services are regularly furnished at permanent units in more than one location, each unit will be independently considered for certification as a rural health clinic. |  This requirement should be checked by surveyor prior to arriving on site. |  |  |
| J22 | **§ 491.5(a)(3) Mobile unit (ii)** 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 a fixed, scheduled location(s). | Date, time and place for each mobile unit day must be listed. The schedule of times and locations must be posted on the mobile unit, but must also be publicized by other means that patients could consult in advance, e.g., on a website, in local libraries or stores, etc. Scheduled locations must meet the rural and shortage location requirements. |  |  |
| **J21** | **§ 491.5(c) The facility meets rural area requirements under one of the following criteria.** |
| J21 | **§ 491.5(c)(1)** Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau. | Requirement should be checked by surveyor prior to arrival. |  |  |
| J21 | **§ 491.5(c)(3)** Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural. | Requirement should be checked by surveyor prior to arrival. |  |  |
| **J21** | **§ 491.5(d) The facility meets the shortage area requirements under one of the following criteria.** |
| J21 | **§ 491.5(d)(1)** 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; and(iv)The percent of the population with a family income below the poverty level. |  Clinic location is in a current HPSA. Requirement should be checked by surveyor prior to arrival. |  |  |
| J21 | **§ 491.5(d)(2)** Determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Service Act) are:(i) The area served is a rational area for the delivery of primary medical care services;(ii) The ratio of primary care physicians practicing within the area to the resident population; and(iii) The primary medical care manpower in contiguous areas is over utilized, excessively distant, or inaccessible to the population in this area. | Clinic location is in a current MUA. Requirement should be checked by surveyor prior to arrival. |  |  |
|  | **§ 491.5(e)(2)**Medically underserved population. A medically underserved population includes the following:1. A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.
2. A population group that is designated by PHS as having a shortage of personal health services.
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| **J40** | **§ 491.6 Physical plant and environment** |
|  | **§ 491.6(a)** **Construction**The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services. | Hours of operation are posted near the entrance on the outside of the clinic. Exit doors are clearly marked with illuminated signs.Clinic does not have any exposed building materials, i.e. insulation, holes in walls, torn carpets, damaged ceiling tiles, etc.Fire extinguishers are mounted, tagged, maintenance annually and inspected on a monthly basis.Emergency exits routes are free of barriers.Exit sign are appropriately placed and illuminated, not glow in the dark.Exit door(s) prevent unauthorized access from the outside but allows emergency exit from within.Secondary doors are locked at all times. Shatterproof light bulbs are used for all exposed lights or light has a protective covering. |  |  |
| J41 |  | Overhead ceiling lights are free of bugs and debris.List of Hazardous Chemicals is present. \*The OSHA Hazard Communication Standard states, “The practice will maintain a chemical inventory list. A list of all hazardous chemicals at the practice location will be prepared and will include the following information: CHEMICAL NAME, BRAND NAME and/or MANUFACTURER.Safety outlets or plug protectors are present in all outlets including exam tables.Sharps containers are secured to the wall throughout the clinic and are high enough so children can’t reach them. Review CDC guidelines.The clinic has an OSHA-approved eyewash station. The station must be operational with one hand movement, provide a continuous flow of clean water for at least 15 min., and be able to operate hands-free for 15 min.Clean and dirty work surfaces are clearly defined throughout the clinic.Floor plans are posted throughout the clinic in each exam room in the hallways and waiting area.All treatment trays are free of dust and debris. There is nothing under the exam room sinks if used by patients.Closed trash containers are utilized in patient care areas. Open containers are an invitation for little hands. This is a best practice.All patient restrooms have an emergency notification system.  |  |  |
| J42 | **§ 491.6(b) Maintenance. The clinic has a preventive maintenance program to ensure that:** |
| J42 | **§ 491.6(b)(1)**All essential mechanical, electrical, and patient care equipment is maintained in safe operating condition. | All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition.All equipment has been labeled, inspected tested and maintained in accordance with manufacturer’s recommendations.Equipment policy includes list of equipment, how the equipment is organized, labeled and tested.Clinic has a process for tracking preventative maintenance.Adult and pediatric scales are balanced.Patient care equipment is appropriately calibrated.AED is maintained and tested in accordance with manufacturer recommendations (pads aren’t expired).Equipment log is current and available to the surveyor.Equipment is cleaned and disinfected prior to each patient’s use.No equipment if stored on the floor.Clinic has a cleaning policy and procedure for equipment. |  |  |
| J43 | **§ 491.6(b)(2)** Drugs and biologicals are appropriately stored. | All medications are stored in locked cabinets, cupboards, and/or drawers. Schedule 2 drugs are double-locked. Medications are locked up at the end of each day.Medications, biological, and sterile supplies are inventoried monthly for expiration dates. Storage supply area is secure (if in patient-care area).Multi-injectable vials, ointments, and solutions are dated and initialed when opened and discarded in accordance with hospital or clinic policy. Should be discarded 28 days after opening.Expired medications, biologicals, and supplies are discarded in accordance with hospital or clinic policy.Refrigerator and freezer temperatures are recorded daily; be sure you can provide data logs. Log sheet should be posted and visible.The clinic does not store medications in the door of the refrigerator or freezer.There is a plan in place in case of a power outage.There are no specimens or food in medication refrigerator or freezer.Sample medications are logged out when dispensed to include: Date, Patient Name, Medication, Lot #, Expiration Date, Amt. Dispensed, and NDC #.Controlled substances are inventoried on a weekly basis and stored and dispensed in accordance with State Pharmacy regulations. |  |  |
| J44 | **§ 491.6(b)(3)** The premises are clean and orderly. | Clinic has a housekeeping policy and the clinic is maintained in accordance to that policy.Clinic has closed trash receptacles. Trashcans in patient care areas should have lids. This is a best practice.Flooring is free from hazards. Vinyl is free from cuts, tears or cracks.Patient restrooms are free of staffs’ personal hygiene products. The clinic is free from clutter.Hallways and exits are free of obstructions.Clean and dirty work surfaces are clearly defined. All treatment trays are free of dust and debris.There is nothing under the exam rooms, patient restrooms or lab-drawn station area sinks.Measures to prevent the spread of infectious diseases. * 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, spread of infectious diseases. |  |  |
| **J60** | **§ 491.7 Organizational structure** |
| J61 | **§ 491.7(a)(1)**The clinic is under the medical direction of a physician, and has a health care staff that meets the requirements of **§ 491.8** | The clinic discloses the name and address of the person responsible for medical direction.Medical director must be an MD or DO who holds a current State license.Staff can identify the clinic’s medical director. |  |  |
| J62 | **§ 491.7(a)(2)** The organization’s policies and its lines of authority and responsibilities are clearly set forth in writing. |  The clinic organizational chart is current. |  |  |
| J62 | **§ 491.7(b) Disclosure. The clinic discloses the names and addresses of:** |
| J62 | **§ 491.7(b)(1)**Its owners, in accordance with Section of the Social Security Act (42 USC 132 A-3). | The ownership is disclosed in the policy manual. |  |  |
| J62 | **§ 491.7(b)(2)**The person principally responsible for directing the day-to-day clinic operations. | The practice administrator is clearly identified.All staff can identify the practice administrator by name.The CMS-29 form is up to date. |  |  |
| J62 | **§ 491.7(b)(3)** The person responsible for medical direction. | The clinic has documentation identifying the name and clinic address of the medication director.Staff can identify the clinic’s Medical Director. |  |  |
| **J80** | **§ 491.8 Staffing and Staff Responsibilities** |
| J81 | **§ 491.8(a)(1) Staffing**The clinic has a health care staff that includes one or more physicians and one or more physician’s assistants or nurse practitioners. | Clinic physicians, MD or DO with current state license.Clinic physician assistant/nurse practitioners with current state licenses: if not, a waiver has been requested. |  |  |
| J82 | **§ 491.8(a)(2**)The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section. | Nurse practitioner (NP) holds a current state license an NP.Physician assistant (PA) holds a current State license as a PA.All mid-level practitioners have either a supervisory or collaboration agreement with the supervising/collaborating physician. |  |  |
| J85, J86 | **§ 491.8(a)(3)** The physician assistant, nurse practitioner, nurse-midwife, clinical social worker or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center. In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic. | One NP or PA is an employee of the clinic. |  |  |
| J84 | **§ 491.8(a)(4)**The staff may also include ancillary personnel who are supervised by the professional staff. | All personnel must hold current State licenses when required. All such personnel must be supervised at all times by an APP or physician. Personnel can identify supervisor. |  |  |
| J85 | **§ 491.8(a)(5)**The staff is sufficient to provide the services essential to the operation of the clinic. | The clinic’s schedule reflects appropriate staffing levels. |  |  |
| J86 | **§ 491.8(a)(6)**A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates. | A physician, physician assistant or nurse practitioner is scheduled at all times during patient care hours.The physician assistant/nurse practitioner is scheduled to see clinic patients at least 50% of the patient care hours (on-site available to see patients).Clinic should have schedules to document this for surveyors. |  |  |
| J100 | **§ 491.8(b) Physician responsibilities. The physician performs the following:** |
| J100 | **§ 491.8(b)(1)** The physician provides medical direction for the clinic’s health care activities and consultation for, and medical supervision of the health care staff. | Evidence of supervision and consultation should be found in chart notes. Supervision should also be defined in clinic policy. |  |  |
| J123 | **§ 491.8(b)(2)**In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients. | A physician participated in the development and review of the clinic’s policies.The physician’s participation is documented.Make sure the time period for “periodically” is specified and signatures indicating review are documented at this specified interval. |  |  |
| J100, J101 | **§ 491.8(b)(3)** The physician periodically reviews the clinic’s patient records, provides medical orders and provides medical care services to the patients of the clinic. | The physician has reviewed 10 Dates of Service (only arecommendation) of each mid-level practitioner at least quarterly.The review is documented and shared with the mid-level practitioner. Maintain documentation that this task is complete. |  |  |
| J101, J102 | **§ 491.8(c) Physician’s assistant and nurse practitioner responsibilities.** |
| J102 | **§ 491.8(c)(1)** The physician’s assistant and the nurse practitioner members of the clinic’s staff:1. participate in the development, execution and periodic review of the written policies governing the services the clinic furnishes;
2. Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and
3. Assures that adequate patient health records are maintained and transferred as required when patients are referred.
 | The NP or PA participate in the development and review of clinical policies.The clinic has a referral policy in place, which explains the referral process.The physician assistant/nurse practitioner participated with the physician in the medical record review. If the review did not happen jointly, the physician’s findings were shared with the physician assistant/nurse practitioner (look for a counter signature on chart, or a chart review log with both providers’ signatures).The physician assistant/nurse practitioner’s participation is documented. |  |  |
|  | **§ 491.9 Provision of Services** |
| J121 | **§ 491.9(a) Basic requirements. The clinic is primarily engaged in providing outpatient health services as described in § 491.9(c).** |
| J121 | **§ 491.9(b) Patient care policies.** |
| J121 | **§ 491.9(b)(1)**The clinic’s health care services are furnished in accordance with appropriate written policies, which are consistent with applicable State law. | Clinical policies are consistent with applicable State law. |  |  |
| J123 | **§ 491.9(b)(2)** The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician’s assistants or nurse practitioners. At least one member of the group is not a member of the clinic’s staff. | The Advisory Group has met within the past 24 months to review the clinic’s policies. The policy review must be performed by:* A physician;
* A PA or NP; and
* A member of the group who is a community representative.
 |  |  |
| J124, J125 | **§ 491.9(b)(3)**The policies include: (i) A description of the services the clinic furnishes directly and those furnished through agreement or arrangement;(ii)Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic; and(iii) Rules for the storage, handling and administration of drugs and biologicals. | The policies include:* Description of Services;
* Medical Guidelines - The policy may simply state that conditions are managed in accordance with a specific practice guide. The practice guide location is known by all clinicians.
* Program Evaluation - Performed at least biennially. Maintain documentation the evaluation has taken place.
* Storage, Handling, and Administration of Drugs and Biologicals.

These policies must be complete and specific to the clinic. |  |  |
| J123 | **§ 491.9(b)(4)**These policies are reviewed at least biennially by the group of professional personnel required under (b) (2) above in this section, and reviewed as necessary by the clinic. | The Advisory Group has met within the past 24 months to review the clinic’s policies. Make sure this is documented via signature.The group includes a community representative. |  |  |
| J122 | **§ 491.9(c) Direct services.** |
| J122 | **§ 491.9(c)(1) General**The clinic staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions. | Clinic policy identifies all the services that are performed onsite through the clinic-by-clinic providers and personnel either as employees or as contract services. |  |  |
| J135 | **§ 491.9(c)(2) Laboratory.**The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:1. Chemical examinations of urine by stick or tablet methods or both (including urine ketones);
2. Hemoglobin or hematocrit;
3. Blood sugar;
4. Examination of stool specimens for occult blood;
5. Pregnancy test; and
6. Primary culturing for transmittal to a certified laboratory.
 | External controls are performed on all CLIA-waived tests, if applicable, all reagents, strips, and controls must be in date.External control results are logged. Lab supplies and reagents are inventoried monthly. Expired supplies are disposed of via the biohazard receptacle as appropriate.The clinic has the ability to perform ON-SITE (even if they are part of a hospital):* Urinalysis;
* Blood glucose;
* Hemoglobin or hematocrit;
* Occult stool;
* Pregnancy; and
* Primary culturing.

 Lab work surface is clearly marked “DIRTY” as appropriate to prevent contamination. It is very clear where contaminated equipment goes. The clinic has a process for tracking labs that are referred out. OSHA guidelines are followed. No food or coffee cups are in the lab. |  |  |
| J136 | **§ 491.9(c)(3) 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. | The clinic has drugs for each of the following drug classifications:* Analgesics (while each drug must be considered, all are not required to be stored in clinic):
* Anesthetics (local)
* Antibiotics
* Anticonvulsants
* Antidotes
* Emetic
* Serums
* Toxoids

Clinic must have a policy and procedure for determining what drugs/biologicals are stored to provide emergency services.MD and NP/PA must sign off on the policy.Emergency drug selection is specific to local conditions (i.e., rattlesnake antivenom).If patients are allowed in the clinic before a provider is on the premises, clerical staff have current BLS certifications on file (note: patients cannot be roomed without a provider on-site). Clinic has a spill kit and all staffs are aware of its location. |  |  |
| J140 | **§ 491.9(d) Services provided through agreements or arrangements.** |
| J140 | **§ 491.9(d)(1)**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:1. Inpatient hospital care,
2. Physician(s) services (whether furnished in the hospital, office, patient’s home, a skilled nursing facility, or elsewhere); and

(iii)Additional and specialized diagnostic and laboratory services that are not available at the clinic. | If there is no policy or agreement, the clinic can provide evidence of referral, and patients are accepted and treated i.e., hospital note, consultation note, etc. |  |  |
| J140 | **§ 491.9(d)(2)**If the agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated. | The clinic has consultation letters and discharge summaries filed in paper charts or the EMR as evidence of verbal agreements. |  |  |
| **J150** | **§ 491.10 Patient health records** |
| J151 | **§ 491.10(a)(1) Records systems.**The clinic maintains a clinical record system in accordance with written policies and procedures. | The policy specifies storage and retention of records. Staff should be able to name the person responsible for medical records and state in policy and procedure manual. |  |  |
| J152 | **§ 491.10(a)(2)**A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systemically organized. | The medical records policies clearly state the position ultimately accountable for the medical records. |  |  |
| J152 | **§ 491.10(a)(3)**For each patient receiving health care services, the clinic maintains a record that includes, as applicable: (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings; (iii) All physician’s orders, reports of treatments and medications and other pertinent information necessary to monitor the patient’s progress;(iv) signatures of the physician or other health care professional. | The RHC must have written patient care policies that address the circumstances when the patient’s informed consent to diagnosis or treatment is required.The medical records will be reviewed by the surveyor to determine if the RHC is meeting these requirements. |  |  |
| **J153** | **§ 491.10(b) Protection of record information.** |
| J153 | **§ 491.10(b)(1)** The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use. | The clinic has a confidentiality policy and policies that govern the storage and handling of PHI. Anyone who does not have a legitimate reason to access the records must be prevented from the possibility of doing so. This includes unsupervised cleaning personnel.  |  |  |
| J153 | **§ 491.10(b)(2)** Written policies and procedures govern the use and removal of records from the clinic and the conditions for release of information. | The clinic has a patient authorization for release policy.The clinic has all appropriate HIPAA policies related to release of information to:* Government entities;
* Law enforcement;
* Friends and family;
* Other providers involved in treatment; and
* When transporting records from one facility to another.
 |  |  |
| J153 | **§ 491.10(b)(3)** The patient’s written consent is required for release of information not authorized by law. | The clinic has a patient authorization for release policy. |  |  |
| J153 | **§ 491.10(c)**Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute. | The clinic’s policy is consistent with State law (7 years). |  |  |
| **J160** | **§ 491.11 Program evaluation** |
| J161 | **§ 491.11(a)** The clinic carries out or arranges for a biennial evaluation of its total program. | The clinic has completed a program evaluation within the past 24 months. This is a condition for certification. Maintain documentation that this evaluation was completed. Staff need to know where it is. During an unannounced recertification survey, if the manager is on vacation and no documentation of quality assurance or program evaluation can be presented, a condition-level deficiency will be cited.There is no requirement a meeting must take place.  |  |  |
| **J161, J42** | **§ 491.11(b) The evaluation includes review of:** |
| J161 | **§ 491.11(b)(1)**The utilization of clinic services, including at least the number of patients served and the volume of services. | A review of the clinic’s utilization of services has been performed in the past 24 months that includes:* Total patients served
* Total face-to-face encounters
* Total # of Medicare encounters
* Total # of Medicaid encounters
* Total # of self/private pay encounters
* Total # of third party encounters
* Total # of male encounters
* Total # of female encounters
* Top 10 Diagnostic Codes
* Encounters broken down by age

The clinic must have a policy on the Program Evaluation.This would include how and when it is performed, by whom and what is included in the evaluation. |  |  |
| J161 | **§ 491.11(b)(2)**A representative sample of both active and closed clinic records; and | The clinic’s documentation meets the compliance requirements:* Identification and social data
* Evidence of consent forms
* Pertinent medical history
* Assessment of health status and health care needs of the patient
* Brief summary of the episode, disposition, and instructions to the patient
* Reports of physical examinations, diagnostic and laboratory test results, and consultative findings
* All physician’s orders, reports of treatments and medications and other pertinent information necessary to monitor the patient’s progress
* Signatures of the physician or other health care professional.

A summary of the findings have been presented to the Advisory Group within the past 24 months with recommendations for consideration and approval. |  |  |
| J161 | **§ 491.11(b)(3)** The clinic’s health care policies. | The clinic’s policies have been reviewed by the clinic’s staff and changes have been made as appropriate.The policies and recommended changes have been presented to the Advisory Group within the past 24 months for consideration and approval. |  |  |
| J161,J162 | **§ 491.11(c) The purpose of the review is to determine whether:** |
| J161, J162 | **§ 491.11(c)(1)** The utilization of services was appropriate; | The Advisory Group has reviewed this and found utilization to be appropriate.  |  |  |
| J161, J162 | **§ 491.11(c)(2)**The established policies were followed; and | The Advisory Group has reviewed this and found that policies were followed. |  |  |
| J161, J162 | **§ 491.11(c)(3)** Any changes are needed. | Based on the review of the utilization of services and clinic policies, changes were made. |  |  |
| J162 | **§ 491.11(d)**The clinic staff considers the finding of the evaluation and takes corrective action if necessary. | Corrective action: * Was required; or
* Not required. Document any changes made.
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|  | **§ 491.12 Emergency Preparedness Program** |
| E0001 | **§ 491.12 The clinic must develop and maintain a comprehensive emergency preparedness program. The clinic must comply with all applicable Federal, State, and local emergency preparedness requirements.** |
| E0004 | **§ 491.12(a)**The RHC or FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following: | The RHC must develop and maintain an emergency preparedness plan that is reviewed and updated at least every two years. A checklist can be helpful. |  |  |
| E0006 | **§ 491.12 (a) (1)** Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. | The clinic has completed a risk-assessment based on an all-hazards approach specific to the geographic location of the clinic and encompasses potential hazards. |  |  |
| E0006 | **§ 491.12 (a) (2)** Include strategies for addressing emergency events identified by the risk assessment. |  |  |  |
| E0007 | **§ 491.12 (a) (3)** Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. | How the facility plans to continue operations during an emergency.Who is the population your clinic serves?What are the services the clinic can provide in an emergency.Delegations of authority. Succession plan - Succession planning is a process for identifying and developing internal people with the potential to fill key business leadership positions in the company. |  |  |
| E0009 | **§ 491.12 (a) (4)** 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. | Does the clinic have documentation on contact efforts and collaboration with local tribal, regional, State, and Federal emergency preparedness officials to ensure an integrated response during a disaster or emergency? |  |  |
|  | **Policies and procedures** |
| E0013 | **§ 491.12(b)** The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following: | Are the Policies and procedures developed based on the facility- and community-based risk assessment and communication plan, utilizing an all-hazards approach?Reviewed and updated EP policy and procedures at least every 2 years. Clearly document the date of review and update and what the update entailed. |  |  |
| E0020 | **§ 491.12 (b) (1)** Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients. | Policy and procedure for clinic evacuation.Placement of exit signs throughout the clinic in the event of an evacuation.Ask staff to describe how they would handle a situation in which a patient refused to evacuate.  |  |  |
| E0022 | **§ 491.12 (b) (2)** A means to shelter in place for patients, staff, and volunteers who remain in the facility. | The emergency plan includes policies and procedures for how it will provide a means to shelter in place for patients, staff and volunteers who remain in the clinic. |  |  |
| E0023 | **§ 491.12 (b) (3)** A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records. | Policy and procedure that documents the medical record documentation system the clinic has developed to preserve patient information, protect the confidentiality of patient information, and secure and maintains the availability of records. |  |  |
| E0024 | **§ 491.12 (b) (4)**The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency. | The clinic has included policies and procedures for the use of volunteers and other staffing strategies in its emergency plan.NOTE: RHCs are not required to use volunteers as part of their EP plan. If the clinic does not use volunteers, include a line that states the RHC does have volunteers. |  |  |
|  | **Communication plan** |
| E0029 | **§ 491.12(c)**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 2 years. | The RHC has a written policy on communication. The following must be included in the EP policy and procedures. |  |  |
| E0030 | **§ 491.12(c) (1)**The communication plan must include all of the following:(1) Names and contact information for the following:(i) Staff;(ii) Entities providing services under arrangement;(iii) Patients' physicians;(iv) Other RHCs; and(v) Volunteers. | Include the names and contact information on a list under the communication plan. |  |  |
| E0031 | **§ 491.12(c) (2)** Contact information for the following:(i) Federal, State, tribal, regional, and local emergency preparedness staff; and(ii) Other sources of assistance. | Include the names and contact information on a list under the communication plan. |  |  |
| E0032 | **§ 491.12(c)(3**)Primary and alternate means for communicating with the following:(i) RHC staff; and(ii) Federal, State, tribal, regional, and local emergency management agencies. | The communication plan includes primary and alternate means for communicating with facility staff, Federal, State, tribal, regional and local emergency management agencies.For instance, a primary means of communication may be cellular phones, hard wire lines and the facilities intercom system, whereas the clinic alternate means (given interruption of primary means) may be cell phones, walkie-talkies or other radio devices. |  |  |
| E0033 | **§ 491.12(c) (4**)A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). | Include in the policy how the clinic will share information on the general condition and location of patients. |  |  |
| E0034 | **§ 491.12(c)(5)** 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. | The communication plan includes a means of providing information about the clinic’s needs, and its ability to provide assistance. |  |  |
|  | **Testing and training** |
|  | **Training** |
| E0036 | **§ 491.12(d)** The RHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. | The clinic has policy and procedures on a testing and training program, which is reviewed at least every 2 years. |  |  |
| E0037 | **§ 491.12(d) (1)**The RHC must do all of the following:(i) 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, | All new and existing staff should have EP training and testing.  |  |  |
| E0037 | (ii) Provide emergency preparedness training at least every 2 years. |  |  |  |
| E0037 | (iii) Maintain documentation of the training.(iv) Demonstrate staff knowledge of emergency procedures. | Keep a log to prove training was completed. |  |  |
| E0037 | (v) If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated policies and procedures. | If the EP plan is updated, train staff on changes and document training. |  |  |
|  | **Testing** |  |  |  |
| E0039 | **§ 491.12(d) (2)**The RHC or FQHC must conduct exercises to test the emergency plan at least annually. The RHC must do the following:  | Clinics are required to only conduct one testing exercise on an annual basis, which may be either one community-based full-scale exercise, if available, or an individual facility-basedfunctional exercise. The opposite years (every other year opposite of the full-scale exercises), these providers may choose the testing exercise of their choice, which caninclude either another full-scale, individual facility-based, a mock disaster drill (using mock patients), a tabletop exercise or workshop, which includes a facilitator. |  |  |
| E0039 | (i) Participate in a full-scale exercise that is community-based every 2 years; or | A full-scale exercise is also an operations-basedexercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements. There is also a definition for “community” as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so, facilities have the flexibility to participate in andconduct exercises that more realistically reflect the risks and composition of their communities. Facilities are expected to consider their physical location, agency, and other facility responsibilities and needs of the community when planning or participating in their exercises.  |  |  |
| E0039 | (A) When a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years; or,(B) 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 its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event. | The clinic can provide an After-Action Report (AAR) and any additional documentation used to support the exercise was completed. |  |  |
| E0039 | (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following: |  |  |  |
| E0039 | (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or(B) A mock disaster drill; or(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. |  |  |  |
| E0039 | (iii) Analyze the RHC response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC or FQHC's emergency plan, as needed. | Clinics are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test thesame scenario year after year or the same response processes. The intent is to identify gaps in the clinic’s emergency program as it relates to responding to variousemergencies and ensure staff are knowledgeable on the program. In the event gaps are identified, clinics should update their emergency programs as outlined withinthe requirements for AAR. |  |  |
|  | **Integrated Healthcare Systems** |
| E0042 | **§ 491.12(e**) If an RHC is part of a health care system consisting of multiple separately certified health care facilities that elect to have a unified and integrated emergency preparedness program, the RHC may choose to participate in the health care system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:  |  |  |  |
| E0042 | (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. | The clinic must actively participate in the development of the unified plan. The clinic must have documentation of both the community-based and individual facility-based risk assessments using an all-hazards approach. |  |  |
| E0042 | (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. | Each clinic must maintain individual training records of staff and records all training exercises. |  |  |
| E0042 | (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program. |  |  |  |
| E0042 | (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:(i) A documented community-based risk assessment, utilizing an all-hazards approach. |  |  |  |
| E0042 | (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. | Each RHC must have its own risk assessment. |  |  |
| E0042 | (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively. | The RHC must be identified in the policies and procedures.  |  |  |