



RURAL HEALTH CLINIC PRE-CERTIFICATION PRACTICE TOOL

Updated: March 2016

JTAG	REGULATION	THINGS TO LOOK FOR	MEETS SPECIFICATIONS (Y/N)	ACTION NEEDED/COMMENTS
J3	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.	This regulation relates to scope of practice and the State's Nurse Practice Act. Oregon Nurse Practice Act can be found here: http://www.oregon.gov/osbn/pages/adminrules.aspx . Compliance with this law maybe be observed through out the survey (ie reviewing patient charts).		
J5	§ 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.	<input type="checkbox"/> All clinical staff must have current BLS certificates on file. <input type="checkbox"/> Personnel files must include, employee application, resume (if applicable), current license/certificate, employment forms, performance appraisal.		
J6	§ 491.5 Location of Clinic			
J7	§ 491.5(a) 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.			
J8	§ 491.5(a)(1) 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. 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.	<input type="checkbox"/> This requirement should be checked by surveyor prior to arriving on site		
J9	§ 491.5(a)(2) 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 a fixed, scheduled location(s).	<input type="checkbox"/> Date, time and place for each mobile unit day must be listed.		
J13	§ 491.5(c) The facility meets rural area requirements under one of the following criteria.			
J14	§ 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.		
J15	§ 491.5(c)(2) 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.		
J16	§ 491.5(d) The facility meets the shortage area requirements under one of the following criteria.			
J17	§ 491.5(d)(1) Determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act).	<input type="checkbox"/> Clinic location is in a current HPSA. Requirement should be checked by surveyor prior to arrival.		
J18	§ 491.5(d)(2) Determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Service Act).	<input type="checkbox"/> Clinic location is in a current MUA. Requirement should be checked by surveyor prior to arrival.		
J19	§ 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.	<input type="checkbox"/> Hours of operation are posted on the outside of the clinic. <input type="checkbox"/> Exit doors are identified. <input type="checkbox"/> Clinic does not have any exposed building materials, i.e. insulation, holes in walls, etc. <input type="checkbox"/> Fire extinguishers are inspected on a monthly basis. <input type="checkbox"/> Emergency exits routes are free of barriers. <input type="checkbox"/> Exit sign are appropriately placed. <input type="checkbox"/> Exit door(s) prevent unauthorized access from the outside but allows emergency exit from within. <input type="checkbox"/> Secondary doors are locked at all times. <input type="checkbox"/> Shatter proof light bulbs are used for all exposed lights.		

J20		<input type="checkbox"/> Eyewash: 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. <input type="checkbox"/> Overhead ceiling lights are free of bugs and debris. <input type="checkbox"/> 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 <input type="checkbox"/> Plug protectors are present in all outlets. <input type="checkbox"/> Sharps are secured throughout clinic. <input type="checkbox"/> The clinic has an OSHA approved eye wash station. <input type="checkbox"/> Clean and dirty work surfaces are clearly defined. <input type="checkbox"/> Floor plans were posted throughout the clinic <input type="checkbox"/> All treatment trays are free of dust and debris <input type="checkbox"/> There is nothing under the exam room sinks. <input type="checkbox"/> Closed trash containers are utilized in patient care areas. Open containers are an invitation for little hands. <input type="checkbox"/> Patient bathroom has an emergency notification system.		
J21	§ 491.6(b) Maintenance. The clinic has a preventive maintenance program to ensure that:			
J22	§ 491.6(b)(1) All essential mechanical, electrical and patient care equipment is maintained in safe operating condition.	<input type="checkbox"/> All equipment has been inspected as of: _____ <input type="checkbox"/> Adult and pediatric scales are balanced <input type="checkbox"/> Patient care equipment is appropriately calibrated <input type="checkbox"/> AED is maintained and tested in accordance with manufacturer recommendations (pads aren't expired) <input type="checkbox"/> Equipment log is current and available to the surveyor		
J23	§ 491.6(b)(2) Drugs and biologicals are appropriately stored.	<input type="checkbox"/> All medications are stored in locked cabinets, cupboards, and/or drawers. Schedule 2 drugs should be double locked. <input type="checkbox"/> Medications are locked up at the end of each day <input type="checkbox"/> Medications, biological, and sterile supplies are inventoried monthly for expiration dates <input type="checkbox"/> Multi-injectable vials, ointments, and solutions are dated when opened and discarded in accordance with hospital or clinic policy. Should be discarded 30 days after opening <input type="checkbox"/> Expired medications, biologicals, and supplies are discarded in accordance with hospital or clinic policy <input type="checkbox"/> Refrigerator and freezer temperatures are recorded daily; and twice daily if storing vaccines. Logs should be posted and visible. <input type="checkbox"/> The clinic does not store medications in the door of the refrigerator or freezer <input type="checkbox"/> Sample medications are logged out when dispensed to include: Date, Patient Name, Medication, Lot #, Expiration Date, Amt. Dispensed, and NDC #. <input type="checkbox"/> Controlled substances are inventoried on a weekly basis and stored and dispensed in accordance with State Pharmacy regulations.		
J24	§ 491.6(b)(3) The premises are clean and orderly.	<input type="checkbox"/> The clinic has a Housekeeping policy and the clinic is maintained in accordance to that policy <input type="checkbox"/> The clinic has closed trash receptacles. Trash cans in patient care areas should have lids. <input type="checkbox"/> Flooring is free from hazards <input type="checkbox"/> Patient restrooms are free of staffs' personal hygiene products <input type="checkbox"/> The clinic is free from clutter <input type="checkbox"/> Hallways and exits are free of obstructions <input type="checkbox"/> Clean and dirty work surfaces are clearly defined <input type="checkbox"/> All treatment trays are free of dust and debris <input type="checkbox"/> There is nothing under the exam room sinks.		
J25	§491.6(c) Emergency procedures. The clinic assures the safety of patients in case of non-medical emergencies by:			
J26	§ 491.6(c)(1) Training staff in handling emergencies.	<input type="checkbox"/> All staff have participated in emergency training, i.e. fire, evacuation, tsunami, acts of terrorism <input type="checkbox"/> Training is documented. A fire drills is documented annually. <input type="checkbox"/> Staff clearly understands their role in the event of an emergency		
J27	§ 491.6(c)(2) Placing exit signs in appropriate locations.	<input type="checkbox"/> Exit signs are clearly identified. All Exit signs must be illuminated, not glow in the dark.		

		<input type="checkbox"/> Floor plans are posted throughout the clinic and inside exams rooms		
J28	§ 491.6(c)(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.	<input type="checkbox"/> Clinic has an earthquake and or tsunami evacuation plan, as appropriate to the area.		
J29	§ 491.7 Organizational structure			
J31	§ 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	<input type="checkbox"/> The medical director is _____ <input type="checkbox"/> Staff can identify the clinic's medical director		
J32	§ 491.7(a)(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.	<input type="checkbox"/> The clinic organizational chart is current		
J33	§ 491.7(b) Disclosure. The clinic discloses the names and addresses of:			
J34	§ 491.7(b)(1) Its owners, in accordance with Section of the Social Security Act (42 USC 132 A-3).	<input type="checkbox"/> The ownership is disclosed in the policy manual.		
J35	§ 491.7(b)(2) The person principally responsible for directing the	<input type="checkbox"/> The practice administrator is clearly identified <input type="checkbox"/> All staff can identify the practice administrator by name –		
J36	§ 491.7(b)(3) The person responsible for medical direction.	<input type="checkbox"/> The Medical Director is _____ <input type="checkbox"/> Staff can identify the clinic's Medical Director		
J37	§ 491.8 Staffing and Staff Responsibilities			
J38	§ 491.8(a) Staffing- see J 37 sheet for details			
J39	§ 491.8(a)(1) The clinic has a health care staff that includes one or more physicians and one or more physician's assistants or nurse practitioners.	<input type="checkbox"/> Clinic physicians are: _____ <input type="checkbox"/> Clinic physician assistant/nurse practitioners are: _____ <input type="checkbox"/> OR a waiver has been requested		
J40	§ 491.8(a)(2) The staff, i.e., the nurse practitioner(s), physician(s) or physician's assistant(s) meets qualification requirements in section 491.2(b), (c), (d).	<input type="checkbox"/> Nurse practitioner holds a current state license as a nurse practitioner <input type="checkbox"/> Physician assistant holds a current State license as a physician assistant <input type="checkbox"/> All Midlevel practitioners have either a supervisory or collaboration agreement with the supervising/collaborating physician		
J41	§ 491.8(a)(3) A physician, nurse practitioner, or physician's assistant is available to furnish patient care services at all times during the clinic's regular hours of operation. A nurse practitioner or a physician's assistant is available to furnish patient care services during at least 50% of the clinic's	<input type="checkbox"/> A physician, physician assistant or nurse practitioner is scheduled at all times during patient care hours <input type="checkbox"/> 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) <input type="checkbox"/> Clinic should have schedule to document this for surveyors		
J42	§ 491.8(a)(4) The staff is sufficient to provide the services essential to the operation of the clinic.	<input type="checkbox"/> The clinic's schedule reflects appropriate staffing levels		
J45	§ 491.8(b) Physician responsibilities			
J46	§ 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.	<input type="checkbox"/> Evidence of supervision and consultation should be found in chart notes. Supervision should also be defined in clinic policy.		
J47	§ 491.8(b)(2) In conjunction with the physician's assistant and/or nurse practitioner member(s), the physician participates in developing, executing and periodically reviewing the clinic's written policies and the services provided to	<input type="checkbox"/> A physician participated in the development and review of the clinic's policies <input type="checkbox"/> The physician's participation is documented <input type="checkbox"/> Make sure the time period for "periodically" is specified and signatures indicating review are documented at this specified interval.		
J48	§ 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.	<input type="checkbox"/> The physician has reviewed 10 Dates of Service (only recommendation) of each Mid-level practitioner at least quarterly <input type="checkbox"/> The review is documented and shared with the Mid-level practitioner. Maintain documentation that this is completed.		

J49	<p>§ 491.8(b)(4) A physician is present for sufficient periods of time, to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section, and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic.</p>	<p><input type="checkbox"/> The physician reviews the documented care of the Mid-level practitioner (a good rule of thumb is 10 records per mid-level per quarter)</p> <p><input type="checkbox"/> The two week rule is no longer in effect. Rather the physician is on site at reasonable intervals to provide supervision. The State Operations Manual Appendix G was updated 4/1/15. It states that the physician must perform the dutiesbut does not need to be on site in order to perform all of these duties. The physician no longer has to be present in the clinic at least once every 2 weeks. Documentation that the physician has completed the required tasks must be maintained.</p>		
J50 § 491.8(c) Physician's assistant and nurse practitioner responsibilities.				
J51	<p>§ 491.8(c)(1) The physician's assistant and the nurse practitioner members of the clinic's staff: (i) participated in the development, execution and periodic review of the written policies governing the services the clinic furnishes; (ii) provide services in accordance with those policies; (iii) arrange for, or refer patients to needed services that cannot be provided at the clinic; (iv) assure that adequate patient health records are maintained and transferred as required when patients are referred; and (v) participates with a physician in a periodic review of the patient's health records.</p>	<p><input type="checkbox"/> A physician assistant or nurse practitioner participated in the development and review of the clinic's policies</p> <p><input type="checkbox"/> The physician assistant/nurse practitioner's participation is documented</p> <p><input type="checkbox"/> The physician assistant/nurse practitioner participated with the physician in the medical record review. If the review didn't happen jointly, the physician's findings were shared with the physician assistant/nurse practitioner (look for counter signature on chart, or a chart review log with both providers signatures)</p>		
J52 § 491.9 Provision of Services				
J53 § 491.9(a) Basic requirements. The clinic is primarily engaged in providing outpatient health services as described in § 491.9(c).				
J54 § 491.9(b) Patient care policies.				
J55	<p>§ 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.</p>	<p><input type="checkbox"/> Written policies are consistent with clinic operations.</p>		
J56	<p>§ 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.</p>	<p><input type="checkbox"/> The Advisory Group has met within the past 12 months to review the clinic's policies.</p> <p><input type="checkbox"/> The Group includes a community representative</p>		
	<p>§ 491.9(b)(3) The policies include: (i) a description of the services the clinic furnishes directly and those furnished through agreement or arrangement;</p>	<p><input type="checkbox"/> The policies include medical guidelines, and program evaluation</p> <p><input type="checkbox"/> Program evaluation should occur annually. Maintain documentaion that this has taken place.</p>		

J57	(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.	<input type="checkbox"/> For medical guidelines, the policy book may simply state that conditions are managed in accordance with a specific practice guide. Just make sure the practice guide location is known by all clinicians. These policies must be complete and specific to the clinic. Refer to the Appendix G of the State Operations Manual.		
J58	§ 491.9(b)(4) These policies are reviewed at least annually by the group of professional personnel required under (b)(2) above in this section, and reviewed as necessary by the clinic.	<input type="checkbox"/> The Advisory Group has met within the past 12 months to review the clinic's policies. Make sure this is documented via signature <input type="checkbox"/> The Group includes a community representative		
J59	§ 491.9(c) Direct services.			
J60	§ 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 healthcare delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.	<input type="checkbox"/> 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.		
J61	§ 491.9(c)(2) Laboratory. The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including: (i) chemical examinations of urine by stick or tablet methods or both (including urine ketones); (ii) hemoglobin or hematocrit; (iii) blood sugar; (iv) examination of stool specimens for occult blood; (v) pregnancy test; and (vi) primary culturing for transmittal to a certified laboratory.	<input type="checkbox"/> External controls are performed on all CLIA waived tests, if applicable <input type="checkbox"/> External control results are logged <input type="checkbox"/> Lab supplies and reagents are inventoried monthly. Expired supplies are disposed of via the bio-hazard receptacle as appropriate <input type="checkbox"/> 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 - primary culturing <input type="checkbox"/> Lab work surface is clearly marked "DIRTY" as appropriate to prevent contamination. It is very clear where contaminated equipment goes. <input type="checkbox"/> The clinic has a process for tracking labs that are referred out. <input type="checkbox"/> OSHA Guidelines are followed <input type="checkbox"/> No food or coffee cups are in the lab		
J62	§ 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.	<input type="checkbox"/> The clinic has drugs for each of the following drug classifications: - analgesics - anesthetics (local) - antibiotics - anticonvulsants - antidotes - emetic - serums - toxoids <input type="checkbox"/> All clinical staff have current BLS certifications on file <input type="checkbox"/> Emergency drug selection is specific to local conditions (ie rattle snake antivenom)		

		<input type="checkbox"/> If patients are allowed into the clinic prior to a provider being on the premises, clerical staff have current BLS certifications on file (note that patients cannot be roomed without a provider on-site) <input type="checkbox"/> Clinic has a spill kit, all staffs are aware of its location.		
J63	§ 491.9(d) Services provided through agreements or arrangements.			
J64	§ 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: (i) inpatient hospital care, (ii) physician(s) services (whether furnished in the hospital, the office, the 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.	<input type="checkbox"/> The clinic has MOAs with nursing homes that it utilizes for patient placement <input type="checkbox"/> If the physician does not have hospital privileges, the clinic has a MOA with the hospital regarding care referred to them by the clinic		
J65	§ 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.	<input type="checkbox"/> The clinic has consultation letters and discharge summaries filed in paper charts or the EMR as evidence of verbal agreements.		
J66	§ 491.10 Patient health records			
J67	§ 491.10(a) Records systems.			
J68	§ 491.10(a)(1) The clinic maintains a clinical record system in accordance with written policies and procedures.	<input type="checkbox"/> Make sure the policy specifies storage and retention of records. Staff should be able to name the person responsible for medical records and state in policy & procedure manual		
J69	§ 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.	<input type="checkbox"/> The medical records policies clearly states who is ultimately accountable for the medical records.		
J70	§ 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.	<input type="checkbox"/> Make sure the charts also notes allergies and expected reactions, as well as severity.		
J71	§ 491.10(b) Protection of record information.			
J72	§ 491.10(b)(1) The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.	<input type="checkbox"/> 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.		
J73	§ 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.	<input type="checkbox"/> The clinic has a patient authorization for release policy <input type="checkbox"/> The clinic has all appropriate HIPAA policies related to release of information to: - Government entities		

J73		<ul style="list-style-type: none"> - Law Enforcement - Friends and Family - Other providers involved in treatment via facsimile - When transporting records from one facility to another 		
J74	<p>§ 491.10(b)(3) The patient's written consent is required for release of information not authorized by law.</p>	<input type="checkbox"/> The clinic has a patient authorization for release policy		
J75	<p>§ 491.10(c) Retention of records.</p>	<input type="checkbox"/> The clinic's policy is consistent with State law (7 years)		
J76	§ 491.11 Program evaluation			
J77	<p>§ 491.11(a) The clinic carries out or arranges for an annual evaluation of its total program.</p>	<input type="checkbox"/> The clinic has completed a program evaluation within the past 12 months. This is a condition for certification. It is a good idea to 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.		
J78	§ 491.11(b) The evaluation includes review of:			
J79	<p>§ 491.11(b)(1) The utilization of clinic services, including at least the number of patients served and the volume of services;</p>	<input type="checkbox"/> A review of the clinic's utilization of services has been performed in the past 12 months that includes: <ul style="list-style-type: none"> - 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 		
J80	<p>§ 491.11(b)(2) A representative sample of both active and closed clinic records; and</p>	<input type="checkbox"/> The clinic's documentation meets the compliance requirements as outlined in J70: <ul style="list-style-type: none"> -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. <input type="checkbox"/> A summary of the findings have been presented to the Advisory Group within the past 12 months with recommendations for consideration and approval.		
J81	<p>§ 491.11(b)(3) The clinic's health care policies.</p>	<input type="checkbox"/> The clinic's policies have been reviewed by the clinic's staff and changes have been made as appropriate. <input type="checkbox"/> The policies and recommended changes have been presented to the Advisory Group within the past 12 months for consideration and approval.		
J82	§ 491.11(c) The purpose of the evaluation is to determine whether: Answers to the point below should be stated in the written program evaluation report.			
J83	<p>§ 491.11(c)(1) The utilization of services was appropriate;</p>	<input type="checkbox"/> The Advisory Group has reviewed this; and found utilization to be appropriate		
J84	<p>§ 491.11(c)(2) The established policies were followed; and</p>	<input type="checkbox"/> The Advisory Group has reviewed this; and found that policies were followed		
J85	<p>§ 491.11(c)(3) Any changes are needed.</p>	<input type="checkbox"/> Based on the review of utilization of services and clinic policies, changes were made		
J86	<p>§ 491.11(d) The clinic staff considers the finding of the evaluation and takes corrective action if necessary.</p>	<input type="checkbox"/> Corrective action: <ul style="list-style-type: none"> - was required or - not required 		