| **RURAL HEALTH CLINIC SURVEY WORKSHEET** | | | | | | | **PROVIDER NUMBER** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NAME OF CLINIC** | | | | | **STREET NUMBER** | **CITY** | **COUNTY** | | **STATE** | **ZIP CODE** |
| **SURVEYED BY** | | | | | **SURVEYOR’S PROFESSIONAL TITLE**   * **INITIAL SURVEY** * **RESURVEY** | | | | **DATE SURVEYED** | |
| **LIST ADDITIONAL SURVEYOR’S NAMES TITLE** | | | | | | | | **PARTICIPATION UNDER TITLES 18 AND 19**  **A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.** | | |
| **Code** | **Yes** | **No** | **N/A** | **I. §491.3 Certification procedures** | | | | **EXPLANATORY STATEMENTS** | | |
| J2 |  |  |  | * MET * NOT MET   **§405.2412 Physicians’ services – standard level tag**  **Physicians’ 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.**  Survey Procedures:   * Ask the leadership of the RHC, and physician(s) at the RHC when applicable, whether or not physician services are ever provided outside the RHC facility. If yes, ask the RHC to see the written agreement(s) and determine whether it contains the required provisions governing payment, certification and Medicare cost reporting. | | | |  | | |
| J3 |  |  |  | * MET * NOT MET   **§405.2416 Visiting nurse services.**  **(a) Visiting nurse services are covered if the services meet all of the following:**  **(1) The RHC… is located in an area in which the Secretary has determined that there is a shortage of home health agencies.**  **(2) The services are rendered to a homebound individual.**  **(3) The services are furnished by a registered professional nurse of licensed practical nurse that is employed by, or receives compensation for the services from the RHC…**  **(4) The services are furnished under a written plan of treatment that is both of the following:**  **(i) (A) Established and reviewed at least every 60 days by a supervising physician of the RHC…’ or**  **(B)(1) Established by a nurse practitioner, physician assistant or certified nurse midwife; and**  **(2) Reviewed at least every 60 days by a supervising physician.**  **(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC…**  **(b) The nursing care covered by this section includes the following:**  **(1) 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.**  **(2) 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.**  **(d) For purposes of this section, 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. For this purpose, “place of resident” does not include a hospital or long term care facility.**  **§405.2417 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.**  Survey Procedures:   * Review personnel files of staff making VNS visits, to ensure that they are currently licensed as either an RN or an LPN. * Review a sample of records of patients receiving VNS to determine; * Whether there is a written treatment plan for each patient, established and signed by an RHC physician or non-physician practitioner. * Whether there is evidence that the plan was reviewed by an RHC physician at least every 60 days; * Whether the clinical record documents the provision of VNS to the patient in accordance with the written plan for that patient. * Observe at least one VNS visit, if any have been scheduled during the survey period, to determine whether care is being provided in accordance with the written treatment plan for that patient. | | | |  | | |
| J10 |  |  |  | * MET * NOT MET   **§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. | | | |  | | |
| J11 |  |  |  | * MET * NOT MET   **§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.**  **Other Federal Requirements**  Survey Procedures:   * Refer suspected noncompliance to the appropriate Federal agency having jurisdiction (e.g., blood-borne pathogens issues to the Occupational Safety and Health Agency; controlled drug accountability issues to the Drug Enforcement Agency; etc.) | | | |  | | |
| J12 |  |  |  | * MET * NOT MET * N/A   **§491.4(a) Licensure of clinic.**  **The clinic… is licensed pursuant to applicable State and local law.**  Survey Procedures:   * Prior to the survey, determine whether the RHC is subject to State or local licensure requirements. * If applicable, verify that the RHC has a current state or local license – this may be done prior to the survey. If not verified independently prior to the survey, ask to see the RHC’s license while on-site. * If the surveyor identifies a situation that suggests the RHC may not be in compliance with any State or local licensure law, the information should be referred to the appropriate licensing authority for follow-up. | | | |  | | |
| J13 |  |  |  | * MET * NOT MET   **§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.**  Survey Procedures:   * Verify that RHC staff and personnel are licensed, certified, or registered, as applicable. * Verify that the RHC has established, and follows procedures for determining that personnel are properly licensed, certified, and/or permitted. * Verify that the RHC has established, and implements, policies and procedures to verify that personnel working at the RHC under contract or arrangement hold whatever license, registration, or certification is required under State law. * Review a sample of personnel files of clinical staff to verify that licensure or other required credential information is present and up to-date. | | | | PHYSICIAN(S) NAME DEA/LICENSURE CURRENT?  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NURSE PRACTITIONER(S) NAME DEA/LICENSURE CURRENT?  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PHYSICIAN ASSISTANT(S) NAME DEA/LICENSURE CURRENT?  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  OTHER LICENSED PERSONNEL - IDENTIFY DEA/LICENSURE CURRENT?  1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| J20 |  |  |  | * MET * NOT MET   **§491.5 Location of clinic**  Depending on the manner and degree of noncompliance with the standards of this condition, condition-level noncompliance may be cited. | | | |  | | |
| J21 |  |  |  | * MET * NOT MET   **§491.5(a) Basic requirements**  **(1) An RHC is located in a rural area that is designated as a shortage area.**  Survey Procedures:   * Prior to conducting an initial on-site survey, make a preliminary assessment as to whether the RHC applicant meets the basic location requirements by reviewing the Form CMS-29 Verification of Clinic Data – Rural Health Clinic Program. * Verify, once on-site, that the location listed on the Form CMS-29 is the same as the location where services are actually being provided. | | | |  | | |
| J22 |  |  |  | * MET * NOT MET   **§491.5(a)(3) …the RHC… may be permanent or mobile units**  Survey Procedures:   * Determine whether the RHC has available in its permanent structure or mobile unit all of the objects, equipment, and supplies required for the provision of RHC clinical services. * If the RHC is a mobile unit, or has a mobile unit in addition to its permanent structure, determine whether it has a publicly available schedule for the upcoming times and locations of mobile RHC services. Determine whether the RHC has posted schedules on the unit as well as provided public notice by other means. * Determine whether the mobile location(s) meet the rural and shortage locations requirements. | | | |  | | |
| J23 |  |  |  | * MET * NOT MET   **§491.5(a)(3)… the RHC… may be permanent or mobile units.**  **(iii) 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.**  Survey Procedures:   * If the RHC has a webpage, check to see if the RHC holds itself out to the public as having multiple permanent locations. * Ask RHC staff members whether the RHC has any other locations, other than mobile units. | | | |  | | |
| J40 |  |  |  | * MET * NOT MET   **§491.6 Physical plant and environment**  Depending on the manner and degree of noncompliance with the standards within this condition, there may be condition-level noncompliance. | | | |  | | |
| J41 |  |  |  | * MET * NOT MET   **§491.6(a) 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.**  Survey Procedures:   * Observe whether the clinic’s physical plan is well constructed and arranged, and does not present barriers to patient access of hazards to patient safety. * Observe whether the clinic has sufficient space given for the type and scope of services provided and the number of patients served. | | | |  | | |
| J42 |  |  |  | * MET * NOT MET   **§491.6(b) Maintenance:**  **The clinic… has a preventative maintenance program to ensure that:**  **(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;**  Survey Procedures:   * Is there documentation that mechanical or electrical equipment is regularly inspected, tested and maintained in accordance with the manufacturer’s recommendations? * If documentation is missing, ask to see the clinic’s policies and procedures for equipment maintenance, to determine whether the problem is with content of the policies and procedures, and or with failure to follow policies and procedures. * Ask staff to provide a copy of or access to copies of the manufacturer’s recommendations for mechanical or electrical equipment. * Ask staff whether there have been any problems with equipment breakdowns or malfunctions. If yes, ask for maintenance documentation for the equipment in question. | | | |  | | |
| J43 |  |  |  | * MET * NOT MET   **[The clinic…has a preventative maintenance program to ensure that:]**  **§491.6(b)(2) Drugs and biologicals are appropriately stored; and**  Survey Procedures:   * Verify drugs are stored according to manufacturer instructions. * Verify that drugs are not accessible to unauthorized individuals/personnel. | | | |  | | |
| J44 |  |  |  | * MET * NOT MET   **[The clinic…has a preventative maintenance program to ensure that:]**  **§491.6(b)(3) The premises are clean and orderly**  Survey Procedures:   * Observe whether all areas which patients use or in which they may receive clinic services are clean and orderly, including the waiting area(s), the exam rooms(s), office space, rest rooms, floors, horizontal surfaces, patient equipment, mechanical rooms, central supply, and storage areas, etc. * As a resource, applicable questions from Part 2 of the ASC surveyor infection control worksheet, Exhibit 351 of the SOM, may be used to assist with identifying the types of observations surveyors should make in an RHC with respect to hand hygiene, injection practices, and, when applicable, single-use devices, high-level disinfection and point-of-care devices. This form may be used to assist RHC surveyors; however, it is not a required RHC form. | | | |  | | |
| J60 |  |  |  | * MET * NOT MET   **§491.7 Organizational structure.**  Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance. | | | |  | | |
| J61 |  |  |  | * MET * NOT MET   **§491.7(a) Basic requirements.**  **(1) The clinic… is under the medical direction of a physician, and has a health care staff that meets the requirements of §491.8.**  **(b) Disclosure. The clinic… discloses the names and addresses of: …**  **(3) The person responsible for medical direction.**  Survey Procedures:   * Verify that the clinic has documentation identifying the name and address of its medical director. * Confirm that the individual identified in the documentation is an MD or DO and still practicing at the RHC. * Confirm that the medical director holds a current license issued or recognized by the State where the clinic is located. Ask staff who the clinic’s medical director is and confirm that the same individual is the one the RHC disclosed as its medical director. * If an already certified RHC clinic has no permanent medical director at the time of the survey, ask for documentation of when the previous medical director ceased performing that function, and of the efforts the RHC has made to fulfill the requirement. | | | |  | | |
| J62 |  |  |  | * MET * NOT MET   **§491.7(a) Basic requirements.**  **(2) The organization’s policies and its lines of authority and responsibilities are clearly set forth in writing.**  **(b) Disclosure. The clinic… discloses the names and addresses of: …**  **(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);**  **(2) The person principally responsible for directing the operations of the clinic…**  Survey Procedures:   * Ask the clinic to provide a copy of its organizational chart and any supporting documentation that articulates the lines of authority and responsibilities of clinic officers and personnel. * Ask the clinic to identify the person who is principally responsible for day-to-day operations. * Ask to see the clinic’s current administrative and clinical policies. Do not review the content of these policies; just confirm that the clinic has written policies. * Verify the clinic owner as captured on the CMS-29 * Verify the names and addresses of the required disclosures are available in the RHCs written records. | | | |  | | |
| J80 |  |  |  | * MET * NOT MET   **§491.8 Staffing and Staff Responsibilities.**  Depending on the manner and degree of noncompliance identified for standards within this condition, there may be condition-level noncompliance. | | | |  | | |
| J81 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(1) The clinic… has a health care staff that includes one or more physicians…**  **(2) The physician member of the staff may be the owner of the rural health clinic, and employee of the clinic…, or under agreement with the clinic… to carry out the responsibilities required under this section.**  Survey Procedures:   * Confirm that the clinic has at least one physician who is providing physician services. Confirm that the physician has a current license issued or recognized by the State in which the RHC is located. | | | |  | | |
| J82 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(1) … Rural health clinic staffs must also include one or more physician’s assistants or nurse practitioners.**  **(3) The physician assistant, nurse practitioner… may be the owner or an employee of the clinic…, or may furnish services under the contract to the clinic… In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.**  Survey Procedures:   * Determine that the clinic has at the time of the survey at least one NP or PA who is an employee of the clinic, as evidenced by the clinic issuing a W-2. * If the clinic already participates in Medicare as an RHC and does not employ a NP or PA, check whether there is a valid waiver in effect. | | | |  | | |
| J83 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(3) The… 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…**  Survey Procedures:   * If the clinic has a nurse midwife, clinical social worker, or clinical psychologist on staff, verify that the individual has a current State license when one is required under State law. | | | |  | | |
| J84 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(4) The staff may also include ancillary personnel who are supervised by the professional staff.**  Survey Procedures:   * Determine whether all clinical staff members who are not practitioners have a current State license or certification, as required. * Ask clinical staff members who are not practitioners to identify their supervisor(s).. * Is there someone responsible for supervising non-practitioners on the clinical staff at all times the RHC is providing services? Request the name of that individual. Interview other clinical staff to confirm. | | | |  | | |
| J85 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(5) The staff is sufficient to provide the services essential to the operation of the clinic…**  **(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… operates…**  Survey Procedures:   * Determine whether there is a physician or a non-physician practitioner on-site at all times the RHC is open. Review staff schedules and the clinic’s hours of operation to confirm. Ask staff members if the RHC is ever open and providing services when no practitioner is present. * Verify posted hours to confirm appropriate professional healthcare staffing within the RHC’s hours of operation. | | | |  | | |
| J86 |  |  |  | * MET * NOT MET   **§491.8(a) Staffing.**  **(6) …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.**  Survey Procedures:   * Determine what the clinic’s total hours of operation are, starting with its weekly schedule. Review hours listed on sighs, the RHC’s website, if it has one, etc., to determine what the hours of operation are. If the RHC’s schedule varies from week to week, review the schedule for a one month period. * Review staffing scheduled for any NPs, PAs, or CNMs on the clinic’s staff for the previous two months, as well as their upcoming schedule for the next month. * Verify that the total scheduled hours for these types of practitioners are at least 50 percent of the total hours the RHC is open. * Spot check a few clinical records to confirm that the practitioner was actually on-site and seeing patients on several of the days where they were listed as present on the staff schedule. * Review physician’s schedule to assist in verifying that the required medical personnel are on site at all times the RHC is open and operating. | | | |  | | |
| J100 |  |  |  | * MET * NOT MET   **§491.8(b) Physician responsibilities. The physician performs the following:**  **(1) …provides medical direction for the clinic’s… health care activities and consultation for, and medical supervision of, the health care staff.**  **(3) …provides medical orders, and provides medical care services to the patients of the clinic or center.**  Survey Procedures:   * Ask the clinic’s medical director how he or she provides overall medical direction and supervision for the clinic. * Review a sample of pertinent clinic records. Is there evidence in the sample of clinical records reviewed that a physician provided assessment, diagnosis, or treatment services and/or wrote orders for patient testing and/or care? | | | |  | | |
| J101 |  |  |  | * MET * NOT MET   **§491.8(b) Physician responsibilities. The physician performs the following:**  **(3) Periodically reviews the clinic’s …patient records…**  **§491.8(c) Physician assistant and nurse practitioner responsibilities.**  **(1) The physician assistant and the nurse practitioner members of the clinic’s …staff:**  **(ii) Participate with a physician in a periodic review of the patients’ health records.**  Survey Procedures:   * Ask the clinic’s staff what its policy is for the interval at which clinical records will be periodically reviewed. Ask when the last review took place, and request documentation of the review. * If State law requires co-signature of NP and/or PA orders by a physician, is there evidence in the clinical record of such co-signatures? * If the RHC ha more than one physician, ask whether its policy permits physicians to share the responsibility for the periodic record review. * Ask how the RHC ensures that all records of patients care for by non-physician practitioners are periodically reviewed. * Is there documentation supporting that the required reviews have occurred? | | | |  | | |
| J102 |  |  |  | * MET * NOT MET   **§491.8(c) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:**  **(i) Provides services in accordance with the clinic’s… policies;**  **(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic…; and**  **(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.** | | | |  | | |
| J120 |  |  |  | * MET * NOT MET   **§491.9 Provision of services.**  Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance. | | | |  | | |
| J121 |  |  |  | * MET * NOT MET   **§491.9(a) Basic requirements:**  **(1) All services offered by the clinic… are furnished in accordance with applicable Federal, State and local laws; and** | | | |  | | |
| J122 |  |  |  | * MET * NOT MET   **§491.9(a) Basic requirements**  **(2) The clinic… is primarily engaged in providing outpatient health services and meets all other conditions of the subpart.**  **(c) Direct services – (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.**  Survey Procedures:   * Review the clinic’s website, and ask the clinic director to describe the types of services the clinic offers. Does it include specialty services that are not RHC services? If yes: * Review the hours the specialty services are available and the hours RHC services are available, to determine whether the majority of time the RHC provides RHC services. * Review a sample of patient health records covering at least the two previous months to determine the majority of specific services actually furnished. | | | |  | | |
| J123 |  |  |  | * MET * NOT MET   **§491.8(b) Physician responsibilities. The physician performs the following:**  **(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic’s… written policies and the services provided to Federal program patients.**  **§491.8(C) Physician assistant and nurse practitioner responsibilities**  **(1) The physician assistant and the nurse practitioner members of the clinic’s… staff:**  **(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic… furnishes;**  **§491.9(b) Patient care policies…**  **(1) The clinic’s… health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.**  **(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 assistants or nurse practitioners. At least one member is not a member of the clinic… staff.**  **(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic…**  Survey Procedures:   * Review meeting minutes or other documentation to verify that the required types of practitioners actually participate at least biennially in developing the policies and recommending policies to the RHC’s leadership. * Ask the RHC’s leadership if it ever rejects the advice of the practitioners. If yes, how does it ensure that any changes made are clinically appropriate? Does it document the rationale for its rejection of the advice? Is there documentation of the policies recommended by the practitioners as well as of any changes made by the RHC’s leadership? | | | |  | | |
| J124 |  |  |  | * MET * NOT MET   **§491.9(b) Patient care policies.**  **(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…**  Survey Procedures:   * Ask the RHC to provide a copy of its description of services. Is it consistent with services advertised on the RHC’s website or via other media? * Ask the RHC’s medical director to show one or more medical management guidelines and explain their source/how they were developed, as well as how they are used. Do the examples include the required elements? * Ask one or more RHC practitioners to demonstrate how they access the RHC’s medical management policies. Are they familiar with the guidelines applicable to their practice? | | | |  | | |
| J125 |  |  |  | * MET * NOT MET   **§491.9(b) Patient care policies.**  **(3) The policies include:**  **(iii) Rules for the storage, handling, and administration of drugs and biologicals.**  The RHC’s policies must address the following:  **Storage of drugs and biologicals**   * **Proper environmental conditions** * **Security** * **Record keeping for the receipt and disposition of all scheduled drugs**   **Handling drugs and biologicals**   * **Compounding** * **Use of Compounding Pharmacies** * **Expiration & Beyond Use Dates**   **Basic safe practices for medication administration within the RHC**  Survey Procedures:   * Are drugs and biologicals stored in a secure manner? * Are drugs stored in areas not accessible to unauthorized personnel? * When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up? * Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for. * When applicable, determine if the RHC has a system that tracks movement of all scheduled drugs from the point of entry into the RHC to the point of departure, either through administration to the patient, destruction of the drug, or return to the manufacturer. * Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs? * Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the RHC to reconcile and address the discrepancies? * Interview the person responsible for drug storage as well as other RHC staff to determine their understanding of the RHC’s controlled drug policies. * If the RHC uses CSPs and obtains them from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding. * Spot-check to identify if expired of unusable medication, including when applicable medications that are past their BUD, are being used for patient care in the RHC. * Ask what type of personnel administer drugs and biologicals within the RHC, including, if applicable, IVs. Are they practicing within their permitted scope? | | | |  | | |
| J135 |  |  |  | * MET * NOT MET   **§491.9(a) Basic requirements.**  **(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs,…**  **§491.9(c) Direct services**  **(2) Laboratory. These requirements apply to RHCs… The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:**  **(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);**  **(ii) Hemoglobin or hematocrit;**  **(iii) Blood glucose;**  **(iv) Examination of stool specimens for occult blood;**  **(v) Pregnancy tests; and**  **(vi) Primary culturing for transmittal to a certified laboratory.**  Survey Procedures:   * Verify that the RHC offers the 6 required basic laboratory services on site. If it does not, is there a State law that prevents the RHC from doing so? * Verify that all laboratory services are operating under a current, appropriate CLIA certificate, including for additional services provided in the RHC beyond the minimum required 6 basic laboratory services. | | | |  | | |
| J136 |  |  |  | * MET * NOT MET   **§491.9(c) Direct services**  **(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.**  Survey Procedures:   * Verify that the RHC has drugs or biologicals in each of the listed categories on hand for emergencies. * Ask RHC staff how they determine the quantity and specific types of drugs and biologicals to have on hand. How do they ensure that they specified drugs and biologicals are on hand in the quantities specified per RHC policy and have not expired? | | | |  | | |
| J140 |  |  |  | * MET * NOT MET   **§491.9(d) Services provided through agreements or arrangements.**  **(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 or center.**  **(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.**  Survey Procedures:   * Determine whether the RHC has referred arrangements with at least one of each of the specified types of providers and suppliers. * If the referral agreements are not in writing, ask the RHC for evidence that referred patients are being accepted for treatment. | | | |  | | |
| J150 |  |  |  | * MET * NOT MET   **§491.10 Patient health records**  Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance. | | | |  | | |
| J151 |  |  |  | * MET * NOT MET   **§491.10(a) Records system.**  **(1) The clinic… maintains a clinical record system in accordance with written policies and procedures.**  **(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documents, readily accessible, and systematically organized.**  Survey Procedures:   * Verify that the RHC has written policies and procedures governing its clinical record system. * Do not review the policies and procedures unless observations, interviews or record reviews indicate noncompliance with the requirements of the Clinical Records Condition. At that time, ask to review the pertinent policies and procedures to determine whether the noncompliance is based on deficient policies or based upon failure to implement compliance policies. * Verify a professional staff member has been designated responsible for the RHC’s clinical record system. * Ask the responsible individual whether there have been changes in the system, e.g., adoption of a partial or full EHR system, and, if so, for evidence that the RHC’s policies and procedures were updated to reflect the clinical record system currently in use. * If the RHC has an EHR system, immediately after the entrance conference interview, ask the person who is responsible for the RHC’s clinical record system to give an overview of the EHR system, including: * Whether there is one system that is fully integrated throughout the RHC or a hybrid EHR- paper record system. In the case of a hybrid system, have the RHC identify which parts of the RHC use which systems. Ask how the RHC ensures that the clinical record is complete, accurate, and accessible in this hybrid environment: * What the arrangement are in the event of an EHR system failure, to ensure that complete and accurate medical records are accessible; * Observe how staff members use the EHR system to determine whether they are able to access complete clinical record information when needed. When applicable, observe whether or not staff members make entries promptly? * If the RHC shares EHR system with other providers, is the RHC able to demonstrate that the RHC’s clinical records are readily identifiable, distinguishable from other information in the shared system and accessible by appropriate RHC staff members only? * If the RHC uses a partial or whole paper clinical record system, are records legible? * When reviewing sampled clinical records is there evidence that any of the records are inaccurate or incomplete? * Is each entry dated, timed, and authenticated? * If RHC policy permits authorized individuals to make entries on behalf of a practitioner, has the practitioner promptly authenticated the entry? * Is each clinical record systematically organized? * Are the medical records organized in a systematic manner allowing easy retrieval? | | | |  | | |
| J152 |  |  |  | * MET * NOT MET   **§491.10(a) Records system**  **(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 the 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.**  Survey Procedures:   * Determine whether there is a medical history for each RHC patient whose clinical record is reviewed. Is there evidence that a practitioner reviewed the medical history? * Ask the RHC what its policy is for updating a patient’s medical history; ask for documentation of the policy. * When applicable, determine if clinical records in the sample being reviewed include an updated medical history. * Determine whether the RHC has adopted policies and procedures addressing when an informed consent is required. * Determine whether there is an informed consent when required in the medical record, and that it contains the minimum required elements as well as any additional elements required under RHC policy. * In records reviewed, is there evidence of: * The practitioner’s assessment of the patient’s health status and health care needs? * A documented summary of the visit, including the required regulatory information? * Physical examination findings, diagnostic and laboratory test results, and consultative findings. * Are findings and test reports appropriately authenticated by a practitioner? | | | |  | | |
| J153 |  |  |  | * MET * NOT MET   **§491.10(b) Protection of record information.**  **(1) The clinic… maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.**  **(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.**  **(3) The patient’s written consent is required for release of information not authorized to be released without such consent.**  Survey Procedures:   * Verify that only authorized persons are permitted access to clinical records. * Observe the RHC’s security practices for patient records. Are paper clinical records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, or on counters where an unauthorized person could gain access to patient records? * Verify that precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records of information in patient records. * Verify that the RHC has policies and procedures governing disclosure of clinical record information, including when the patient’s written consent is required. | | | |  | | |
| J154 |  |  |  | * MET * NOT MET   **§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 statue.**  Survey Procedures:   * Determine that records are retained for at least 6 years from the date of the last entry. | | | |  | | |
| J160 |  |  |  | * MET * NOT MET   **§491.11 Program Evaluation**  Depending on the manner and degree of noncompliance with any of the standards in this condition, there may be condition-level noncompliance. | | | |  | | |
| J161 |  |  |  | * MET * NOT MET   **§491.11(a) The clinic… carries out, or arranges for, a biennial evaluation of its total program**  **(b) The evaluation includes review of:**  **(1) The utilization of clinic… services, including at least the number of patients served and the volume of services;**  **(2) A representative sample of both active and closed clinical records; and**  **(3) The clinic’s… health care policies.**  **(c) The purpose of the review is to determine whether:**  **(1) The utilization of services was appropriate;**  **(2) The established policies were followed; and**  **(3) Any changes are needed.**  Survey Procedures:   * Is there evidence that the evaluation includes review of the number of patients served and the volume of services provided? * Is there evidence of a review of a representative sample of RHC records? * Does the sample include the required minimum number of records? * Who conducts which portions of the review? Are they qualified to do so? * Is there evidence of findings and recommendations from the review, and do the findings address each required component? | | | |  | | |
| J162 |  |  |  | * MET * NOT MET   **§491.11(d) The clinic… staff considers the findings of the evaluation and takes corrective action if necessary.**  Survey Procedures:   * Does the RHC have documentation of leadership review of the evaluation findings each year? * Is there evidence of the RHC taking corrective actions? * If the RHC did not take recommended corrective actions or took corrective actions different from those recommended, did it document an appropriate rationale supporting its decision? | | | |  | | |