**Montana Critical Access Hospital:**

**RURAL HEALTH CENTER Survey Self-Assessment Tool**

**The Survey Self-Assessment Tool**

This document is part of a series of Survey Self-Assessment Tools created for the Montana Hospital Association specific to Critical Access Hospitals (“CAHs”) and their affiliated facilities and services. Other documents in this series are:

* ***Montana Critical Access Hospital Survey Self-Assessment Tool***
* ***Montana Critical Access Hospital Swing-Bed Survey Self-Assessment Tool***

Critical Access Hospitals (“CAHs”) and the CAH’s affiliated facilities and services must comply with federal requirements in order to participate in Medicare and be eligible to receive Medicare/Medicaid payment. Many CAHs own or operate Rural Health Centers or Clinics (“RHCs”), including RHCs that function as on-or off-campus provider-based entities of the CAH. RHCs are subject to Medicare Conditions for Certification (“CfCs”). The goal of a survey is to determine if the RHC is in compliance with CfCs. Certification of RHC compliance with the CfCs is accomplished through the survey process and involves observations, interviews, and document/record reviews. Surveyors take direction from the [State Operations Manual - Appendix G](https://www.cms.gov/files/document/appendix-g-state-operations-manual) (“SOM”) and use unique identifiers called "J-Tags" to assess compliance with the CoPs. This Survey Self-Assessment Tool (“Tool”) lists each J-Tag which captures the requirements in the CfCs and information from the SOM[[1]](#footnote-1) that details what the surveyors will be assessing. Additionally, below are Survey Preparation Recommendations to assist with considerations prior to a survey being conducted.

**How To Use The Tool[[2]](#footnote-2)**

CAHs may use this Tool to prepare for upcoming surveys or may use the Tool on an ongoing basis to evaluate, identify gaps, and document internal compliance with CAH-specific requirements. Each row of the Tool describes a J-Tag, the underlying CfC, and guidance from the SOM on how the CAH can demonstrate compliance with the J-Tag. Review each row of the Tool and evaluate whether the CAH does or does not comply with the standard. The review should be dated and initialed by the reviewer. Where appropriate, the reviewer should include information in the Notes/Comments column that indicates where applicable compliance documentation can be found or steps that are being taken to address ongoing compliance with the J-Tag. Note that the Tool captures only a summary of the applicable standards, the standard in its entirety may be found in the applicable regulation or SOM cited in the Self-Assessment Questions or Comments column.

**Limitations of The Tool**

This Tool is intended to comprehensively address RHC-specific requirements but is not meant to address all potentially applicable laws and may exclude other relevant requirements (e.g. provider-based, HIPAA/IT, specialty services, etc.). Please ensure that this Tool is used to supplement existing compliance and operational review activities and documents taking into consideration the CAH's and RHC’s specific operations. This Tool does not fulfill RHC-specific requirements itself, but rather provides a mechanism for the CAH to check its internal compliance related to the operation of its affiliated RHCs. The content of this Tool may not be current at all times, as changes occur to applicable laws and to the SOM from time to time.

**SURVEY PREPARATION RECOMMENDATIONS**

1. ***Create a Survey Team within your CAH and Specific to the RHC(s) Being Surveyed***. The team should be responsible for gathering necessary and preferred documentation (and keeping it current), working with department managers and other staff to ensure everyone understands their role in the survey process, and checking for compliance on a regular basis.
2. ***Plan for Surveyor Resources***. To minimize the time and impact of the survey on your facility, plan out the following resources for the survey team[[3]](#footnote-3):
	1. A location (e.g. conference room) at the RHC where the survey team may work privately and conduct interviews, as applicable.
	2. Access to the RHC or related CAH policies, procedures, patient care protocols, and medical records and availability of nurses or staff to help provide access.
	3. Access to a copy machine so that the survey team may make copies of records.
	4. Direct access to the EHR and availability of an IT or other experienced EHR users to help provide access.
3. ***Survey documents***. Have a folder ready with the following documents or have a plan to make the following documents that are updated and current available immediately upon commencement of the survey.
	1. Names, locations, and telephone numbers of key staff to whom questions should be addressed
	2. Map/floor plan
	3. Organizational chart and personnel records
	4. List of all staff providing patient care including the Medical Director, active Medical Staff, Allied Health Professionals, etc.
	5. List of contracted services
	6. Program evaluation or QAPI documentation.
	7. Copy of CLIA or other certifications and the most recent survey documentation
	8. All applicable policies and procedures.
	9. Lists of the following information, all of which include at least the patient’s name, purpose of office visit, and the physician/mid-level furnishing the office visit (this would be compiled upon the surveyor’s entrance to the facility).
		1. All patients scheduled for the date that the survey commences
		2. All office visits from the last six (6) months prior to the date the survey commences.
		3. All cases in the past year prior to the date the survey commences, where the patient was transferred from the RHC to another health care facility for emergency services.
4. ***Policy documentation and processes***. Throughout, certain CfCs refer to the process taken to review and revise certain policies or activities. Although each department should be responsible for the review of their policies, it is important to have a written explanation of how the group or persons described in the applicable J-Tag are involved in this process (e.g. J-Tag J-0123 requires PA and NP participation in review of written policies). Both a description of the process and evidence of this group’s involvement must be readily available for a surveyor’s review.
5. ***Environmental walk-through***. Part of the survey process includes a walk-through of the facility. The survey team makes observations and interviews staff during the walk-through. These observations often lead to further policy review. One of the functions of your survey team should be to periodically conduct a walk-through, observing as a surveyor would.

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*No table of contents entries found.*

**Survey Self-Assessment Tool**

| **Self-Assessment Questions** | **Yes** | **No** | **N/A** | **Date/Name of Reviewer** | **Comments** |
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| ***Certification Procedures*** |
| Has the RHC met the procedures for certification as an RHC and does it maintain its Medicare Agreement and documentation of certification by Medicare as an RHC?J-000142 C.F.R. § 491.342 C.F.R. § 405.2401- 405.2402 |  |  |  |  | \*Note, In general, there are no survey procedures specific to this J-Tag. |
| Are physician services at the RHC furnished by either:1. A physician at the RHC
2. Outside of the RHC, by a physician who has a written agreement with the RHC that provides that he or she will be paid by the RHC for such services and certification and cost reporting requirements are met.

Specifically, for services rendered outside the RHC, does the written agreement between the RHC and physician:1. Specifically provide that the RHC pays the physician for the RHC services provided, and that the RHC will continue to meet Medicare certification and cost reporting requirements?
2. Contain the required provisions governing payment, certification and Medicare cost reporting?

(SOM at 30).J-000242 C.F.R. § 491.342 C.F.R. § 405.2412 |  |  |  |  | \*Note, additional details about services outside the RHC discussed in the SOM (SOM at 30). |
| For visiting nurse services (“VNS”), do the services meet all of the following requirements?1. Is the RHC located in an area in which the Secretary has determined that there is a shortage of home health agencies and the RHC maintains documentation of this determination by the Regional Office?
2. Are the services rendered to a homebound individual?
3. Are the nursing care services furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC?
4. Are the personal care services those covered by Medicare as home health services (helping the patient to bathe, to get in and out of bed, to exercise and to take medications)?
5. Are the services furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the RHC and signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife, that identifies the nursing and personal care services that are provided to the patient?

J-000342 C.F.R. § 491.342 C.F.R. § 405.2416 |  |  |  |  | \*Note, Household and housekeeping services or other services that would constitute custodial care are not covered under Medicare. SOM at 31-32. |

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| ***Compliance with Federal, State and Local Laws*** |
| Is the RHC and its staff in compliance with applicable Federal, State and local laws and regulations?1. Is the RHC licensed pursuant to applicable State and local law?
2. Are the staff of the RHC licensed, certified or registered in accordance with applicable State and local laws?
3. Are all RHC records and personnel files updated to reflect proper licensure and other required credential information?

J-0010 J-001142 C.F.R. **§** 491.4 |  |  |  |  | \*Note, the Montana state licensure requirements in ARM 37.106.310 gives Montana specific guidelines for issuance and renewal of a licenses. |
| Is the RHC licensed pursuant to applicable State and local law?J-0010 J-001242 C.F.R. **§** 491.4(a) |  |  |  |  | \*Note, while RHCs are not independently required to be licensed health care facilities under Montana law, if the RHC is a provider-based entity of the CAH, ensure that the RHC maintains the applicable CAH license and any documentation indicating that the RHC is a provider-based entity of the CAH under that license number. |
| Are the staff of the RHC licensed, certified or registered in accordance with applicable State and local laws and are all RHC records and personnel files updated to reflect proper licensure and other required credential information?Specifically, does the RHC:1. Verify that RHC staff and personnel are licensed, certified, or registered.
2. Establish and follow procedures for determining that personnel are properly licensed, certified, and/or permitted.
3. Establish and implement policies and procedures to verify that contracted personnel are properly licensed, certified, and/or registered, as applicable.

Additionally, at a minimum, does each employee file contain:1. the employee's name
2. a job description signed by the employee
3. documentation of employee orientation, signed by the employee; and
4. a copy of current credentials, certification, or professional licenses required to perform the duties described in the job description.

J-0010 J-001342 C.F.R. **§** 491.4 (b)ARM 37.106.315(2) |  |  |  |  | \*Note, while RHCs are not independently required to be licensed health care facilities under Montana law, if the RHC is a provider-based entity of the CAH, it is a best practice to ensure that the requirements of generally applicable Minimum Standards for All Health Care Facilities are met. ARM 37.106.301 *et seq*. |

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| ***Location of RHC******Note: As indicated below, some of the following location criteria are designated upon the RHC’s’s initial certification by the CMS Regional Office. Only the CMS RO may make a determination as to whether an existing or prospective RHC is located in a rural area that is also designated as a shortage area. The RO relies upon information from: (1) The US Census Bureau as to whether a location is in a rural area; and (2) The Health Services and Resources Administration (HRSA) as to whether a location is in a designated shortage area (SOM at 37).******Note: The following requirements should be closely reviewed prior to survey particularly if any of the following apply:***1. ***CAH moved locations of its main provider or the location of any of its provider-based RHC locations and has not been recertified by the CMS Regional Office;***
2. ***CAH built new RHC which has not been recertified by the CMS Regional Office;***
3. ***CAH added new provider-based RHC locations.***
 |
| Is the RHC located in a rural area that is designated as a shortage area as determined by the CMS Regional Office?Specifically, is the location listed on Form CMS-29 the same as the location where services are actually being provided?SOM at 38.J-0020J-002142 C.F.R. § 491.5 |  |  |  |  | \*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office will help the CAH/RHC assess its compliance with the ***Location*** requirements. |
| If the RHC has a permanent or mobile unit, does the RHC: 1. Directly furnish the objects, equipment, and supplies necessary for the provision of the services; and
2. House the objects, equipment, and supplies in either:
	1. A permanent structure (for a permanent unit); or
	2. In a mobile structure which has a fixed, scheduled location (for a mobile unit).

Specifically, does the mobile units:1. Maintain a publicly available schedule that patients could consult in advance (e.g., on a website, in local libraries or stores, etc.);
2. Ensure that the mobile unit meets the rural area and designated shortage area requirements as determined by the CMS Regional Office.

SOM at 39-40.J-0020J-0022J-002342 C.F.R. § 491.5(a)(3) |  |  |  |  | \*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office will help the CAH/RHC assess its compliance with the ***Location*** requirements. |
| If the RHC is a permanent unit does it only have one permanent unit location or does the RHC qualify for a grandfathered exception?Specifically, to qualify for the grandfathering exception, is the RHC:1. A private, nonprofit facility;
2. That meets all other conditions of this subpart except for location in a shortage area;
3. That prior to July 1, 1977, was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

Additionally, if the RHC recently relocated, does the RHC meet both the rural area and designated shortage area location requirements at the new location? SOM at 41.J-0020J-002442 C.F.R. § 491.5(b)  |  |  |  |  | \*Note, for RHCs, there is a grandfathering provision that permits an existing certified RHC to remain an RHC even if population growth and/or changes in the availability of health care practitioners results in their no longer meeting the location requirements at § 491.5(a)(1). SOM at 41.\*Note: Maintenance of certification, recertification, and necessary provider documentation from the CMS Regional Office will help the CAH/RHC assess its compliance with the ***Location*** requirements. |

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| ***Physical plant and environment*** |
| Is the RHC constructed, arranged, and maintained to ensure access to and safety of patients, and provide adequate space for the provision of direct services?1. Are the RHC’s layout and fixtures free from hazards that increase risk of patient injury, such as slippery floors or torn carpets that may present tripping or fall hazards, or ceilings panels that are in danger of falling, etc.?
2. Is the physical plant designed and constructed in accordance with applicable State and local building, fire, and safety codes?
3. Does the RHC have enough space for the fixtures, equipment and supplies required in order for it to provide those RHC services which must be furnished directly?

J-0040J-004142 C.F.R. § 491.6(a) |  |  |  |  |  |
| Does the RHC have a preventive maintenance program to ensure that all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition?Specifically, does the RHC compile or maintain:1. Documentation that mechanical or electrical equipment is regularly inspected, tested and maintained in accordance with the manufacturer’s recommendations;
2. Policies and procedures for equipment maintenance;
3. Copies of the manufacturer’s recommendations for mechanical or electrical equipment.
4. Maintenance documentation to address equipment breakdowns or malfunctions.

SOM at 43.J-0040J-0042C.F.R. § 491.6(b)(1) |  |  |  |  | . |
| Does the RHC have a preventive maintenance program to ensure that drugs and biologicals are appropriately stored?Specifically, does the RHC ensure that:1. Drugs are stored according to manufacturer instructions.
2. Drugs are not accessible to unauthorized individuals/personnel.
3. Policies and procedures identify which types of RHC staff are authorized to access drugs and biologicals.

SOM at 44.J-0040J-0043C.F.R. § 491.6(b)(2) |  |  |  |  |  |
| Does the RHC have a preventive maintenance program to ensure that the premises are clean and orderly?Specifically does the RHC:1. Appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities?
2. Maintain policies and procedures for an orderly and clean environment, including:
	1. Measures taken to maintain a clean and orderly environment during internal or external construction/renovation;
	2. Measures to prevent the spread of infectious diseases including 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;
	3. Disposal of waste, including medical waste;
	4. Food sanitation, if employee food storage and eating areas are provided; and
	5. Pest control.

J-0040J-0044C.F.R. § 491.6(b)(3) |  |  |  |  | \*Note, CAHs are required to maintain Infection Prevention and Control policies that overlap with some of these requirements and may be used during Surveys. See SOM at 45. To the extent that the RHC is a provider-based entity of the CAH, ensure that the RHC’s practices align with those set forth in the CAH’s underlying Physical Plant and/or Infection Prevention and Control |

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| ***Organizational Structure******Note that for RHCs that are provider-based entities of the CAH, the CAH provides the same monitoring and oversight of the RHC as it does for any other department of the CAH and the organizational structure requirements of these CfCs may also reflect the CAH’s oversight of the provider-based RHC.*** |
| Is the RHC under the medical direction of a physician? Does the RHC have a health care staff that meets the requirements set forth for Tag J-0080 below?Specifically:1. Is the medical director a M.D. or D.O. currently licensed in the state in which the RHC is located, and
2. Does the RHC document the name, address, and phone number of the medical director?
3. Does the RHC immediately notify the appropriate Survey Agency when the medical director changes with the new name, address, phone number, and current license of the new medical director.
4. If the medical director is a locum tenens, (i.e. temporary), is he or she contractually bound to provide services to the RHC for minimum of six months?

J-0060J-006142 C.F.R. §§ 491.7(a) & (b)(3) |  |  |  |  | \*Note, deficiencies in health care staff requirements may be cited under either Tags J-0060 *et seq*. or J-0080 *et seq*. |
| Are the organization’s policies and its lines of authority and responsibilities clearly set forth in writing?Has the RHC disclosed the names and addresses of:1. Its owners; and
2. The person principally responsible for directing the operations of the RHC?

Specifically, does the RHC identify in writing all of the following?1. Maintain a copy of its organizational chart;
2. Maintain written documentation of all types of staff positions, their place in the organizational arrangement, and their functions and responsibilities?
3. Maintain administrative and clinical policies;
4. Ensure that the owner and personnel data for the RHC matches that on Form CMS-29 and CMS-855A.

SOM at 48-49.J-0060J-006242 C.F.R. § 491.7(a)(2) 42 C.F.R. § 491.7(b)(1)-(2)  |  |  |  |  |  |

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| ***Staffing and staff responsibilities******If the RHC is a provider-based entity of the CAH: (i) the medical director maintains the same reporting relationship to the CAH as applicable to other department medical directors and is subject to the same accountability and supervision under the CAH as applied to other department medical directors; (ii) professional staff of the RHC have clinical privileges at the CAH; and (iii) medical staff committees and other professional committees of the CAH are responsible for medical activities, quality assurance, utilization review, and coordination of services between the RHC and the CAH. Accordingly, provider-based RHCs should incorporate these requirements into the implementation of these CfC requirements.*** |
| Does the RHC meet the following physician staffing requirements:1. Does the RHC have a health care staff that includes one or more physicians and at least one M.D. or D.O.?
2. Does the physician hold a current license issued or recognized by the State in which the RHC is located?
3. Is the physician member of the staff the owner of the RHC, an employee of the RHC, or under agreement with the RHC to carry out the responsibilities required under this section?
4. Does the RHC have sufficient physician practitioners to furnish the volume of RHC services it providers to its patients, consistent with accepted standards of practice?

J-0080J-008142 C.F.R. § 491.8(a)(1)42 C.F.R. § 491.8(a)(2) |  |  |  |  |  |
| Does the RHC meet the following non-physician staffing requirements?1. Does the RHC staff also include one or more physician’s assistants or nurse practitioners or have a current waiver of this requirement granted by CMS?
2. Is/are the physician assistant(s) and/or nurse practitioner(s) the owner or an employee of the RHC?
3. Or do the physician assistant(s) and/or nurse practitioner(s) furnish services under contract to the RHC?
4. Is at least one physician assistant or nurse practitioner an employee of the RHC?
5. Does the RHC have sufficient non-physician practitioners to furnish the volume of RHC services it providers to its patients, consistent with accepted standards of practice?

J-0080J-008242 C.F.R. § 491.8(a)(1)42 C.F.R. § 491.8(a)(3) |  |  |  |  | \**See* SOM at 52-53 for detailed instructions on how an existing RHC may request a waiver of the requirement to employ a NP or PA.  |
| Does the RHC meet the following optional staffing requirements?1. Are any nurse-midwife, clinical social worker, or clinical psychologist members of the staff the owner or an employee of the RHC?
2. Or do the nurse-midwife, clinical social worker, or clinical psychologist members of the staff furnish services under contract to the RHC?
3. Are the nurse-midwife, clinical social worker, or clinical psychologist members of the staff licensed as required by State law of the State in which the RHC is located, and practicing within their permitted scope of practice?

J-0080J-008342 C.F.R. § 491.8(a)(3) |  |  |  |  | \*Note, The RHC is not required to have a nurse-midwife, clinical social worker, or clinical psychologist on staff. |
| If the RHC staff includes ancillary personnel, such as registered nurses, licensed practical nurses, laboratory technicians, etc. does the RHC:1. Designate a person who is responsible for supervising non-practitioners on the clinical staff at all times the RHC is providing services?
2. Ensure that ancillary staff holds current State licenses or certifications, as applicable?

SOM at 54.J-0080J-008442 C.F.R. § 491.8(a)(4) |  |  |  |  |  |
| Is the staff sufficient to provide the services essential to the operation of the RHC?Is a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist available to furnish patient care services at all times the RHC operates?J-0080J-008542 C.F.R. § 491.8(a)(5)42 C.F.R. § 491.8(a)(6) |  |  |  |  | \*Note, No health care services may be provided until a mid-level practitioner, clinical social worker, clinical psychologist or physician staff member is present onsite, regardless of whether services are being furnished via telehealth or not. SOM at 56. \*Note that staff schedules, posted RHC hours, and calendars may be reviewed by Surveyors to determine compliance with this condition and J-Tag. SOM at 56-57.  |
| Are the nurse practitioners, physician assistants, and certified nurse-midwifes available to furnish patient care services at least 50 percent of the time the RHC operates?J-0080J-008642 C.F.R. § 491.8(a)(6) |  |  |  |  | \*Note that staff schedules, posted RHC hours, and calendars may be reviewed by Surveyors to determine compliance with this condition and J-Tag. SOM at 56-57. |
| Do the RHC physicians perform the following duties:1. Medical direction for the RHC's health care activities and consultation for, and medical supervision of, the health care staff;
2. Assessment, diagnosis, and treatment of patients;
3. Medical orders, and provide medical care services to the patients of the RHC?

Additionally, does the RHC maintain evidence of the physician’s performance of duties in the pertinent clinical records? SOM at 59. J-010042 C.F.R. § 491.8(b)(1)42 C.F.R. § 491.8(b)(3) |  |  |  |  | \*Note that the requirement for “supervision” does not limit the ability of non-physician practitioners to practice independently within their State scope of practice (e.g. NPs). SOM at 58. |
| Do the physicians periodically review the RHC’s patient records?Do the physician assistants and/or the nurse practitioners participate with the physicians in periodically reviewing the RHC’s patient records either face-to-face or via telecommunications?Specifically, does the RHC:1. Establish the interval at which clinical records will be periodically reviewed in policies;
2. Document physician co-signature of NP and/or PA orders in the clinical record when required by State laws;
3. If the RHC has more than one physician, maintain a policy permitting physicians to share the responsibility for the periodic record review;
4. Ensure that all records of patients cared for by non-physician practitioners are periodically review;
5. Document supporting that the required reviews occurred.

(SOM at 60-61).J-010142 C.F.R. § 491.8(b)(3)42 C.F.R. § 491.8(c)(1)(ii) |  |  |  |  | \*Note, off-site review of the medical record via an electronic medical record system is permissible. SOM at 60-61. |
| To the extent not performed by a physician, are the physician assistants or nurse practitioners performing the following functions:1. Providing services in accordance with the RHC's policies and within the provider’s State-permitted scope of practice?
2. Arranging for, or referring patients to, needed services that cannot be provided at the RHC?
3. Assuring that adequate patient health records are being maintained and transferred as required when patients are referred?

J-010242 C.F.R. § 491.8(c)(2) |  |  |  |  |  |

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| ***Provision of Services******If the RHC is a provider-based entity of the CAH, inpatient and outpatient patient care activities are required to be integrated with those of the CAH and the patients treated at the RHC who require further care must have full access to the services of the CAH and RHC patients are referred, where appropriate, to the corresponding inpatient or outpatient department or service of the CAH. Accordingly, for provider-based RHCs, implementation of these CfCs may involve integration of the CAH’s patient care policies and referrals of patients to the CAH’s patient care services. Note that the RHC may not exclusively refer to the CAH, despite integration and provider-based requirements.*** |
| Are all services offered by the RHC furnished in accordance with applicable Federal, State, and local laws?J-0120J-012142 C.F.R. § 491.9(a)(1) |  |  |  |  |  |
| Is the RHC primarily engaged in providing outpatient health services?Does the RHC staff furnish 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, including medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions?J-0120J-012242 C.F.R. § 491.9(a)(2)(c) |  |  |  |  | \*Note, Surveyors may rely on the RHC’s website, posted hours of operation, and clinical record review to determine the amount of time the RHC dedicates the specialty services to determine compliance with this section. SOM at 64-65. |
| Does the physician, in conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the RHC's written policies and the services provided to Federal program patients? Do the physician assistant and the nurse practitioner members of the RHC's staff participate in the development, execution and periodic review of the written policies governing the services the RHC furnishes?J-0120J-012342 C.F.R. § 491.8(b)(2)42 C.F.R. § 491.8(c)(1)(i) |  |  |  |  |  |
| Does the RHC have patient care policies that:1. Describe the services furnished by the RHC, either directly or through an agreement / arrangement?
2. Provide guidelines for 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 RHC?

Additionally, do RHC practitioners know how to access the RHC’s medical management policies and regularly do so when applicable? (SOM at 67)J-0120J-012442 C.F.R. § 491.9(b)(3)(i) & (ii) |  |  |  |  |  |
| Do the RHC’s written patient care policies address storage, handling, and administration of drugs and biologicals within the RHC?1. Are the policies in accordance with accepted professional principles of pharmacy and medication administration practices?
2. Are the policies in compliance with applicable Federal and State law?
3. Do the policies adhere to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations?

Do the RHC’s policies address the following?1. Storage of drugs and biologicals?
2. Proper environmental conditions?
3. Security?
4. Record keeping for the receipt and disposition of all scheduled drugs?
5. Handling drugs and biologicals?
6. Compounding?
7. Use of compounding pharmacies?
8. Expiration & beyond use dates?
9. Basic safe practices for medication administration within the RHC?

(SOM at 67-72)J-0120J-012542 C.F.R. § 491.9(b)(3)(iii) |  |  |  |  | \*Note, CAHs are required to maintain Drugs and Biologicals policies that overlap with and exceed those requirements applicable to RHCs. To the extent that the RHC is a provider-based entity of the CAH, ensure that the RHC’s practices align with those set forth in the CAH’s underlying Drugs and Biologicals Policy.\*Note, there is significantly more detail included in the SOM than is listed here. The SOM details what should be included in the provisions listed here and should be reviewed for evaluation of compliance with this section, particularly if the RHC does not adopt the underlying Drugs and Biologicals Policy of the CAH. (SOM Appx G pg. 67-73) |
| Does the RHC provide basic laboratory services essential to the immediate diagnosis and treatment of the patient?1. Chemical examinations of urine by stick or tablet method or both (including urine ketones)?
2. Hemoglobin or hematocrit?
3. Blood glucose?
4. Examination of stool specimens for occult blood?
5. Pregnancy tests?
6. Primary culturing for transmittal to a certified laboratory?

Are these laboratory services being provided in accordance with the clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR Part 493 operating under a current CLIA certificate appropriate to the level of services performed?(SOM at 74)J-0120J-013542 C.F.R. § 491.9(c)(2) |  |  |  |  | \*Note, Consult 42 CFR Part 493 - LABORATORY REQUIREMENTS for comprehensive guidelines on laboratory requirements and the implementation of the provisions of section 353 of the Public Health Service Act. |
| Does the RHC provide medical emergency procedures as a first response to common life-threatening injuries and acute illness?Does the RHC have available the drugs and biologicals commonly used in life saving procedures, including but not limited to: 1. Analgesics;
2. Anesthetics (local);
3. Antibiotics;
4. Anticonvulsants;
5. Antidotes and emetics,
6. Serums and toxoids?

Additionally, 1. Does the RHC maintain written policies and procedures to determine the types and quantities of drugs / biologicals it stores for medical emergency purposes?
2. When determining which drugs and biologicals the RHC has available for purposes of addressing common life-threatening injuries and acute illnesses, has the RHC considered, among other things, the community history, the medical history of its patients and accepted standards of practice?
3. Is the RHC able to provide a complete list of the drugs/biologicals that are stored and in what quantities?
4. Are RHC staff aware of or trained to determine the quantity and specific types of drugs and biologicals to have on hand per RHC policy, and to ensure that the drugs and biologicals have not expired?

(SOM at 75) J-0120J-013642 C.F.R. § 491.9(c)(3) |  |  |  |  | \*Note, CAHs are required to maintain Drugs and Biologicals policies that overlap with and exceed those requirements applicable to RHCs. To the extent that the RHC is a provider-based entity of the CAH, ensure that the RHC’s practices align with those set forth in the CAH’s underlying Drugs and Biologicals Policy. |
| Does the RHC have agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients? Specifically, does the RHC have a referral agreement with at least one Medicare / Medicaid-participating: 1. Hospital or CAH for inpatient acute care;
2. Physician for professional services;
3. Diagnostic testing facility (which could be a hospital or CAH or freestanding diagnostic testing facility) for ambulatory diagnostic tests not furnished in the RHC; and
4. Clinical laboratories for clinical laboratory services.

(SOM at 76).If the agreements are not in writing, is there evidence that patients referred by the RHC or center are being accepted and treated? J-0120J-014042 C.F.R. § 491.9(d)  |  |  |  |  |  |

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| ***Patient Health Records******Note that to the extent the RHC is a provider-based entity of the CAH, the entities are required to have integrated or cross-referenced medical records for provider-based purposes. In that case, ensure that the RHC follows the CAH’s clinical record policies and procedures, including record retention schedules, and that the CAH’s clinical record policies captures those requirements that are specific to the RHC CfCs and the services furnished by the RHC. Note that the CAH requirements both overlap with and exceed the requirements applicable to RHC and as such CAH policies and procedures will govern. Freestanding RHCs will be independently subject to the CfC requirements listed below.*** |
| Does the RHC maintain a clinical record system in accordance with written policies and procedures?Is a designated member of the professional staff responsible for maintaining the records and for insuring that they are completely and accurately documented, legible, readily accessible, and systematically organized?Specifically:1. Does the RHC have written policies and procedures governing its clinical record system that are updated to reflect the clinical record system currently in use?
2. If the RHC has a hybrid EHR-paper record system, can it identify which parts of the RHC use which systems and ensure completeness, accuracy, and accessibility in the hybrid environment?
3. Does the RHC have arrangements in the event of an EHR system failure to ensure that complete and accurate medical records are accessible when needed?
4. If the RHC uses an integrated EHR system with other providers can the RHC readily identify its information separate from other information in the shared system?
5. If the RHC uses an integrated EHR system with other providers, is the RHC’s records only accessible by appropriate RHC staff members only?
6. Does the RHC maintain a complete, comprehensive, legible, and accurate clinical record (also referred to as a medical record) for each RHC patient that is readily accessible to the RHC staff?
7. Is each entry dated, timed, and authenticated?
8. If RHC policy permits authorized individuals to make entries on behalf of a practitioner, has the practitioner promptly authenticated the entry?
9. Is each clinical record systematically organized?
10. Are the medical records organized in a systematic manner allowing easy retrieval?

J-0150J-015142 C.F.R. § 491.10(a)(1)-(2) |  |  |  |  | \*Note that as indicated in the header to this section, provider-based RHCs will follow the CAH’s clinical records policies and procedures.  |
| For each patient receiving health care services, does the RHC maintain a record that includes the following? (as applicable)1. Identification and social data,
2. Evidence of consent forms,
3. Pertinent medical history,
4. Assessment of the health status and health care needs of the patient,
5. A brief summary of the episode, disposition, and instructions to the patient
6. Reports of physical examinations, diagnostic and laboratory test results, and consultative findings
7. All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress
8. Signatures of the physician or other health care professionals.

J-0150J-015242 C.F.R. § 491.10(a)(3) |  |  |  |  | \*Note, there is significantly more detail included in the SOM than is listed here. The SOM details what should be included in the provisions listed here and should be reviewed for evaluation of compliance with this section. (SOM Appx G pg. 81-84) |
| Does the RHC maintain the confidentiality of record information and provide safeguards against loss, destruction or unauthorized use?Does the RHC maintain written policies and procedures that govern the use and removal of records from the RHC or center and the conditions for release of information?Does the RHC maintain that the patient's written consent is required for release of information not authorized to be released without such consent?J-0150J-015342 C.F.R. § 491.10(b) |  |  |  |  |  |
| Does the RHC retain its patient’s medical records retained for at least 6 years from date of last entry (specifically, the date of the patient’s discharge or death, or closure of the facility)? J-0150J-015442 C.F.R. § 491.10(c)ARM 37.106.314(2) |  |  |  |  | \*Note, while RHCs are not independently required to be licensed health care facilities under Montana law, if the RHC is a provider-based entity of the CAH, it is a best practice to ensure that the requirements of generally applicable Minimum Standards for All Health Care Facilities are met. ARM 37.106.301 *et seq*.\*Note that as indicated in the header to this section, provider-based RHCs will follow the CAH’s clinical records policies and procedures, including any record retention schedules maintained by the CAH.  |
| Does the RHC carry out, or arrange for, a biennial evaluation of its total program, including number of patients serviced and the volume of services provided?Does this evaluation include the review of the following:1. The utilization of RHC 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 of at least 5% of the RHC’s current patients or 50 records, whichever is less?
3. Practitioner evaluations, conducted by an M.D. or D.O.
4. Whether the RHC complies with its patient care policies?

(SOM at 87)J-0160J-016142 C.F.R. § 491.11(a)-(c) |  |  |  |  | \*Note that to the extent the RHC is provider-based entity of the CAH, the CAH’s QAPI Program and medical staff committees are responsible for the utilization review, quality assurance, and program evaluation activities of the provider-based RHC. To the extent that the CAH’s QAPI Program meets or exceeds these requirements, it will fulfill the RHC’s program evaluation standard for Tag J-0161. The CAH’s underlying QAPI Program should include the provider-based RHC and address any unique characteristics of the provider-based RHC.\*Note, a RHC that has been certified for less than one year may not have done a program evaluation. However, the RHC must have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered within the evaluation. |
| Does the RHC staff consider the findings of the evaluation and take corrective action if necessary?Specifically, 1. Did the RHC document leadership review of the evaluation findings and the recommendations considered?
2. Did the RHC also document what corrective actions, if any, were taken and by whom they were recommended?
3. If the RHC leadership does not take corrective actions recommended as part of the evaluation, or if it takes corrective actions different from those recommended, has it documented the rationale for its decision?

(SOM at 88)J-016242 C.F.R. § 491.11(d) |  |  |  |  |  |

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1. Although there are multiple appendices to the State Operations Manual, for purposes of this Tool, all references to “SOM” are references to the [State Operations Manual - Appendix G](https://www.cms.gov/files/document/appendix-g-state-operations-manual) (as linked) or as found at the following web address: <https://www.cms.gov/files/document/appendix-g-state-operations-manual> and which may be updated from time to time. [↑](#footnote-ref-1)
2. Completion of this Tool in its entirety and ongoing holistic review of the organization’s compliance with the standards captured in the Tool is a best practice and will ensure that the organization is optimally prepared for survey.  However, given time and resource limitations, it may be desirable to prioritize certain categories for self-assessment based on historical survey results or ongoing areas of concern.  [↑](#footnote-ref-2)
3. This level of access is permitted and in fact required by the CAH’s provider agreement with Medicare. [↑](#footnote-ref-3)